PENTAX™

OWNER'S MANUAL

GI FIBERSCOPES

FD-34V/34V2
FG-16V FG-24V FG-29V
FC-38MV FC-38MV2
FC-38FV FC-38FV2
FC-38LV
FS-34V

IMPORTANT

Prescription Statement

Federal (U.S.A) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

Intended Use (Duodenoscope)

The Duodenoscope is intended to provide optical visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes, but is not restricted to, the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts.

This instrument is introduced per orally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

Intended Use (Gastoroscopes)

These Gastroscopes are intended to provide optical visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes, but is not restricted to, the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum and Small Bowel.

These instruments are introduced per orally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

Intended Use (Colonoscopes and Sigmoidoscopes)

These Colonoscopes and Sigmoidoscopes are intended to provide optical visualization of, and therapeutic access to, the Lower Gastrointestinal Tract. The Lower Gastrointestinal Tract includes, but is not restricted to, the organs, tissues, and subsystems: Large Bowel.

These instruments are introduced per rectally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

Sterility Statement

The instruments identified in this instructional booklet are reusable medical devices. Since they are packaged non-sterile, they must be high-level disinfected or sterilized BEFORE initial use. Prior to each subsequent procedure, they must be subjected to an appropriate cleaning and either high-level disinfection or sterilization process.

Conventions

Throughout this manual, the following conventions will be used to indicate a potentially hazardous situation which, if not avoided;

⚠ WARNING : could result in death or serious injury.

CAUTION : may result in minor or moderate injury or property-damage.

NOTE : may result in property-damage. Also, advises owner/operator about important information on the use of this equipment.

Notes

Read this manual before operating, and save this book for future reference. Failure to read and thoroughly understand the information presented in this manual, as well as those developed for ancillary endoscopic equipment and accessories, may result in serious injury to the patient and/or user, Furthermore, failure to follow the instructions in this manual may result in damage to, and/or malfunction of, this equipment. If you have any questions regarding any of the information in this manual or concerns pertaining to the safety and/or use of this equipment, please contact your local Pentax representative.

The text contained in this manual is common for various types/models of Pentax endoscopes and users must carefully follow only those sections and instructions pertaining to the specific instrument models appearing on the front cover.

This manual describes the recommended procedures for inspecting and preparing the equipment prior to its use and for the cleaning and maintenance of the equipment after its use. It does not describe how an actual procedure is to be performed, nor does it attempt to teach the beginner the proper technique or any medical aspects regarding the use of the equipment.

It is the responsibility of each medical facility to ensure that only well educated and appropriately trained personnel, who are competent and knowledgeable about the endoscopic equipment, antimicrobial agents/processes and hospital infection control protocol be involved in the reprocessing of these medical devices. Known risks and/or potential injuries associated with flexible endoscopic procedures include, but are not limited to, the following: perforation, infection, hemorrhage, burns and electric shock.

Current infection control guidelines require that G. I. scopes and other semi-critical medical devices, that normally come into contact with intact mucous membranes, such as in the gastrointestinal tract, should at least be high-level disinfected before clinical use. Only the user can determine if an instrument has undergone appropriate infection control procedures prior to each clinical use. It must be recognized that infection control practices involve many complex and often controversial issues which are constantly evolving. Pentax strongly recommends that user remain informed of the latest federal and local regulations, and encourages users to follow infection control guidelines developed by various organizations for health care professionals.

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⚠ *WARNING:*

Instrument repairs should only be performed by an authorized Pentax service facility. Pentax assumes no liability for any patient/user injury, instrument damage or malfunction, or ***REPROCESSING FAILURE*** *due to repairs made by unauthorized personnel.*

1. NOMENCLATURE AND FUNCTION

1-1. FIBERSCOPE

UP/DOWN DEFLECTION LOCK:
When this lever is in the "F" position turned clockwise, the bending section moves freely. When turned counterclockwise, the bending section becomes progressively more stabilized.

SUCTION CONTROL VALVE (Part # OF-B120):
Depress to remove fluids or air through the instrument channel. Part # of the O ring set for the valve is OF-B127.

SERIAL NUMBER

AIR/WATER FEEDING VALVE (Part # OF-B121):
Covering of hole in the top of the valve delivers pressurized air. Covering of the hole and fully depressing the valve delivers pressurized water. Part # of the O ring set for the valve is OF-B143.

IMMERSIBLE MARKING
The blue line here indicates the scope is fully immersible.

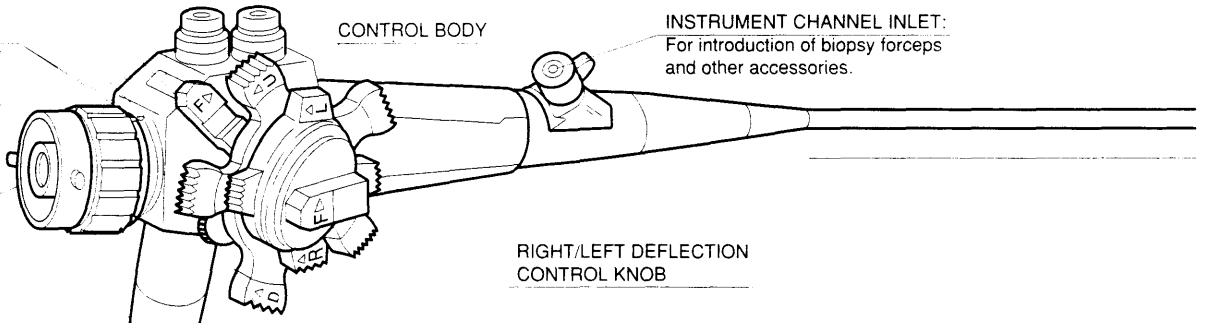
MODEL DESIGNATION

RUBBER INLET SEAL
Allows passage of accessories while preventing escape of fluids and air.

DIOPTER POSITION MARKS (WHITE)
Must be aligned to ensure proper focus for photography and use with an assistant observerscope.

CONTROL BODY

INSTRUMENT CHANNEL INLET:
For introduction of biopsy forceps and other accessories.



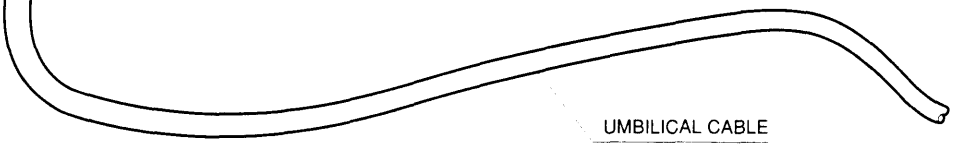
RIGHT/LEFT DEFLECTION CONTROL KNOB

RIGHT/LEFT DEFLECTION LOCK:
Functions similar to Up/Down lock.

UP/DOWN DEFLECTION CONTROL KNOB

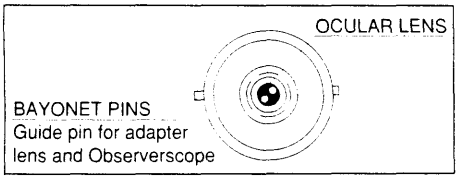
CANNULA ELEVATOR CONTROL KNOB
(DUODENOSCOPES ONLY)
To guide and direct cannula or forceps.

DIOPTER ADJUSTMENT RING:
Adjustable for individual user's eyesight.



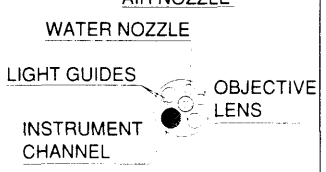
UMBILICAL CABLE

EYEPIECE

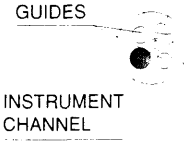


FG-16V GASTROSCOPE

FG-24V/29V GASTROSCOPES



FC-38V SERIES COLONOSCOPE



AIR NOZZLE
Directs pressurized air across objective lens to remove moisture, also provides distension of cavity being examined.

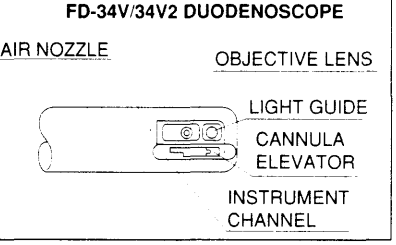
WATER NOZZLE
Directs pressurized water across objective lens to clear debris.

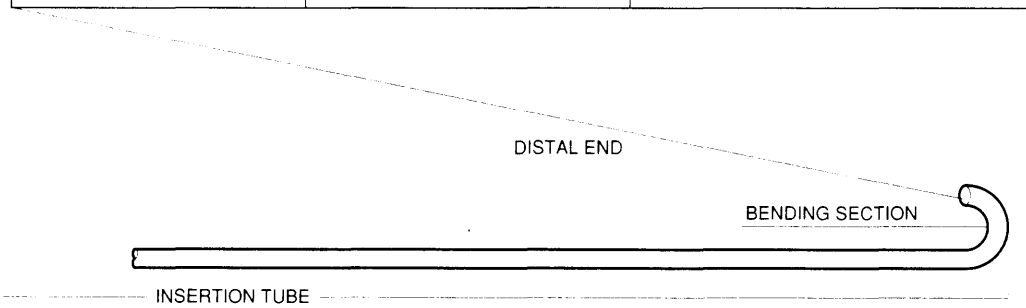
FS-34V SIGMOIDOSCOPE

AIR NOZZLE
Directs pressurized air across objective lens to remove moisture, also provides distension of cavity being examined.

WATER NOZZLE
Directs pressurized water across objective lens to clear debris.

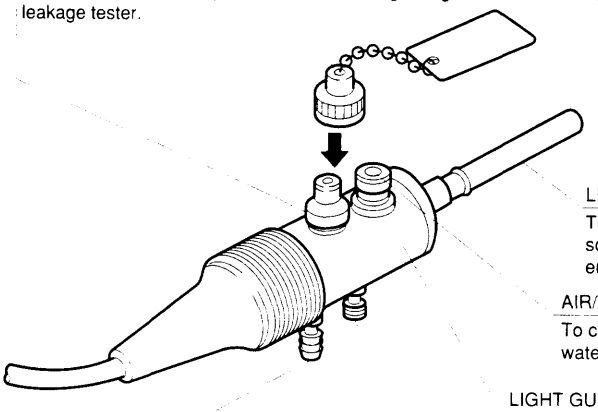
FD-34V/34V2 DUODENOSCOPE





ETO STERILIZATION VENTING CAP RED (MODEL: OF-C5):
Provides venting of endoscope interior to equalize internal and external pressures. This cap must be removed before immersion.
NOTE: See important separate section regarding the use of this cap!

VENTING CONNECTOR:
Accepts "RED" ETO Sterilization Venting Cap. Also accepts leakage tester.



LIGHT GUIDE:
Transmits light from light source to distal end of endoscope.

AIR/WATER CONNECTOR:
To connect feeding tube from water bottle assembly.

LIGHT GUIDE CONNECTOR

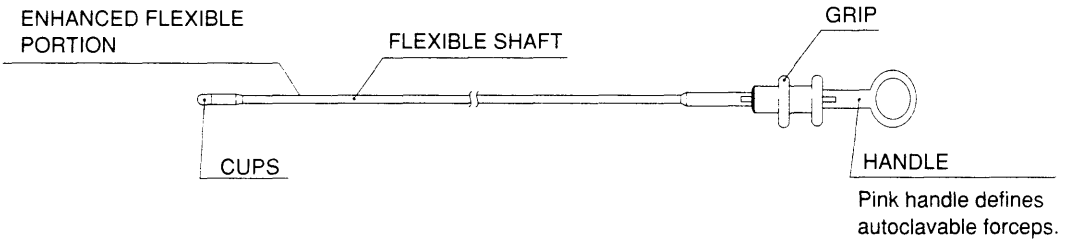
SUCTION NIPPLE:
For attachment to external suction source.

FEEDBACK TERMINAL
Certain manufacturers' electrosurgical units, such as Olympus, require the connection of a scope feedback cord (S-cord) to this feedback terminal.

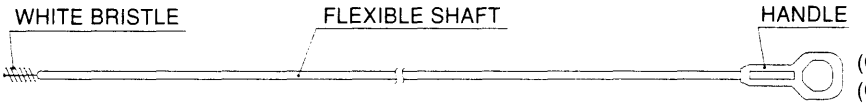
> ⚠ *WARNING:*
>
> Immediately after use, the metal light guide prong of the endoscope may be HOT.
> To avoid burns, do not touch these areas immediately after use. For safer handling after a procedure, grasp the plastic light guide plug.

1-2. ACCESSORIES

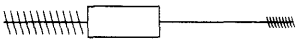
1) Biopsy Forceps



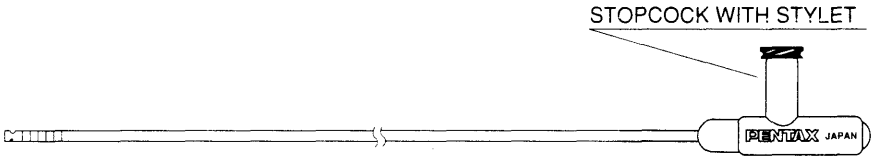
2) Cleaning Brush for Instrument Channel



3) Cleaning Brush for A/W Suction Valve Cylinder



4) Cannula **(DUODENOSCOPES ONLY)**



CAUTION:

Because of the effect that accessories used through the instrument channel of the endoscope can have on the performance of the endoscope itself, it is strongly recommended that PENTAX accessories be used with PENTAX endocopes. If a unique or highly specialized accessory is available from another source, please contact PENTAX to arrange a test of its compatibility before using it through the PENTAX endoscope.

NOTE:

For patient contact endoscopic accessories, follow the specific and detailed instructions on use, care and maintenance supplied with each product.

NOTE:

Maxumum outer diameter of an endoscopic accessory instrument must be at least 0.2 mm less than the specified instrument channel diameter in Pentax endoscopes.

Working length of an endoscopic accessory instrument may be approximately 30 cm longer than the endoscope working length.

-3. LIGHT SOURCE

NOTE

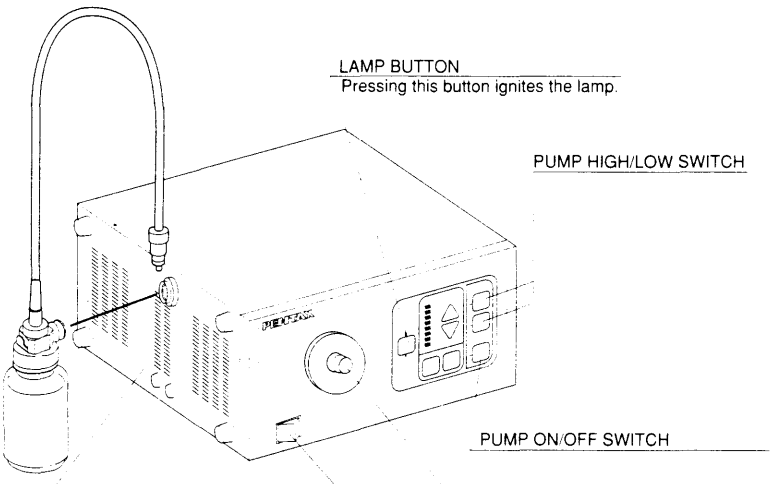
Do not use the new Pentax OS-H4 water bottle cap with the older OS-H2 water container/bottle. Although the cap may appear to fit onto the bottle, air may escape resulting in insufficient pressure and flow of air and water during the endoscopic procedure. Both the Pentax water bottle cap and bottle (container) are identified by their appropriate model designation. Ensure that an OS-H4 cap is used only with the OS-H4 water container/bottle.

Do not overtighten the bottle cap. Overtighting can cause the bottle cap to break.

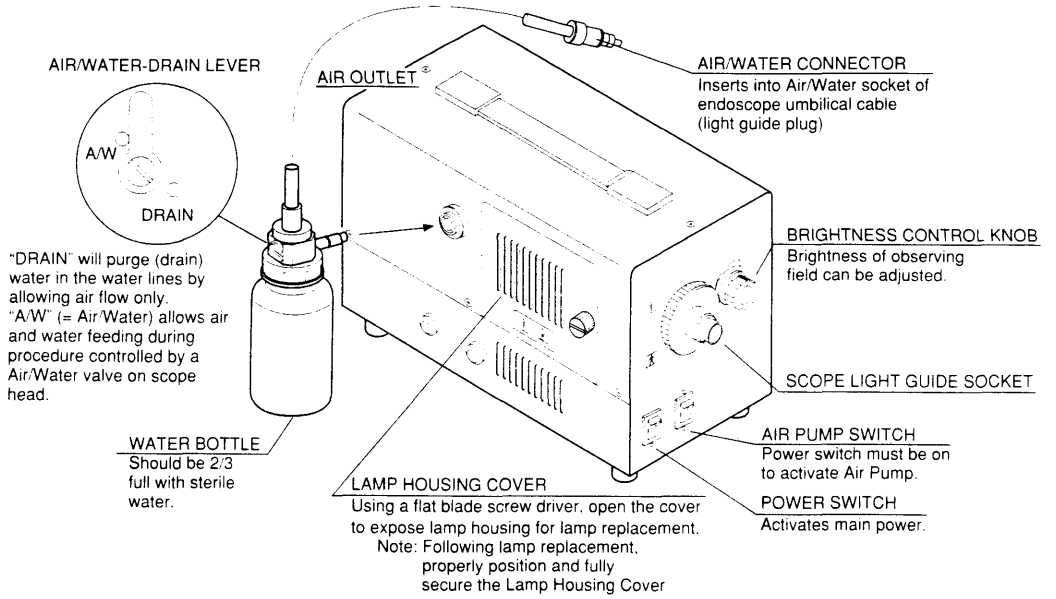
⚠ *WARNING:*

- *Avoid places where the light source may be splashed with liquid.*
- *Absolutely DO NOT use in any environment with explosive or flammable gases or chemicals.*
- *Do not block the ventilation grids on the sides of the light source.*
- *Do not install, operate or store electro-medical equipment in a dusty environment Accumulation of dust within these units may cause malfunction, smoke, or ignition.*
- *Please refer to the instruction supplied with the light source.*

LX-750P



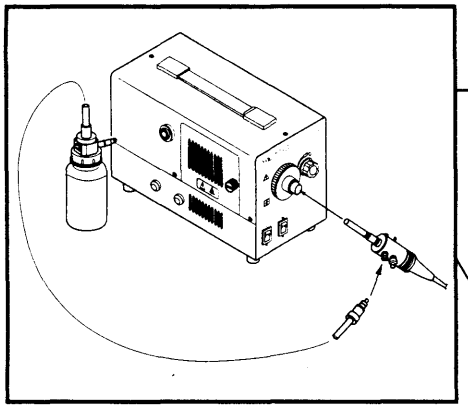
LH-150PC



2. PREPARATION AND INSPECTION FOR USE

Prior to use, the endoscope, light source and accessories must be carefully inspected for cleanliness and proper function to determine that they are appropriate for patient use.

2-1. INSPECTION OF LIGHT SOURCE



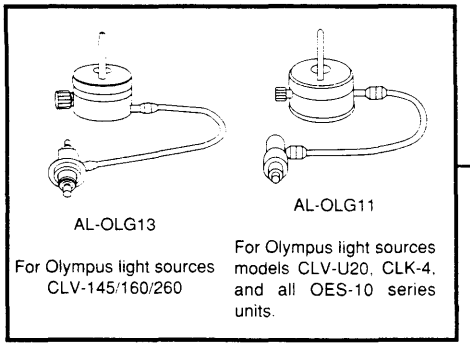
Please refer to the operating manual of the PENTAX light source involved for complete instructions.

1) Attach water bottle assembly, 2/3 filled with sterile water to the appropriate location on the light source.

> ⚠ *WARNING:*
> *The addition of defoaming agents to the water supply is NOT recommended. Due to their nature, these silicone based agents cling tenaciously to surfaces. Unless they are rinsed very thoroughly, a "barrier" could be created which could reduce the effectiveness of the disinfection/ sterilization process. Additionally, repeated use of such defoamers could eventually lead to residual silicone build up resulting in equipment malfunction such as clogged air and/or water channels.*

2) Set the drain lever on the water bottle assembly to the A/W (air/water) position.

3) With the power switch in OFF position, plug light source into a properly grounded receptacle. Pentax light sources have a hospital grade plug with a grounding conductor.



AL-OLG13

For Olympus light sources CLV-145/160/260

AL-OLG11

For Olympus light sources models CLV-U20, CLK-4, and all OES-10 series units.

4) Adapters are available to connect Pentax fiberscopes to Olympus light sources. For assistance, please contact your local Pentax distributor or service facility.

5) Make sure the Pentax light guide receptacle is properly aligned with the two indicators on the front panel of the light source.

6) Connect the endoscope light guide plug to the light source.

7) Connect the air/water feeding tube from the water bottle assembly to the air/water connector.

8) Turn on the light source and the air pump to check for proper functioning.

> *CAUTION:*
> *To avoid thermal injury and to protect the user's eye from high intensity light, it is recommended to select the brightness level as low as possible.*

⚠ *WARNING:*

The risk of thermal injury exists whenever fiberoptic instruments are used with high intensity light sources.

The risk of injury is greatest:

(A) When a high intensity Xenon light source, is used.

(B) During close stationary observation and/or prolonged close contact with mucosa.

(C) When the fiberscope is advanced slowly through a narrow lumen.

Close stationary viewing should be avoided and the level of illumination should be limited to the level necessary for adequate visualization.

⚠ *WARNING:*

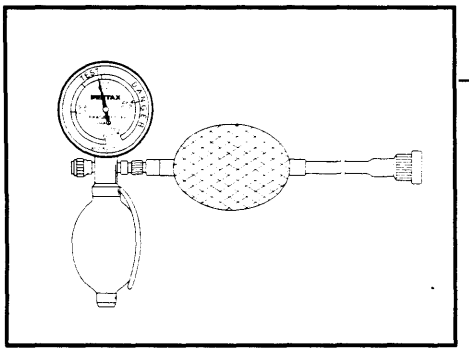
The automatic brightness control mode of the LX-750P should NOT be used with these scopes since there is no photosensor control circuitry within these instruments. The risk of thermal injury exists because in the absence of this electrical system, the LX-750P, when in the automatic brightness mode, will transmit maximum illumination.

2-2. INSPECTION OF FIBERSCOPE

CAUTION:

If the endoscope is intended to be clinically used after testing of individual scope functions (suction, air/water delivery, etc.) without further reprocessing, the following precaution should be exercised.

Use "fresh" distilled or sterile water during individual scope function tests to avoid recontamination of the previously reprocessed instrument by waterborne microorganisms. Tap water, especially that which may be left idle and uncovered for a prolonged period of time, should not be used during any inspection/testing of the endoscope.



Leakage Tester

Before proceeding with inspection of individual functions, PENTAX Fiberscopes should be tested for the integrity of their water-tight design (example: tear in the instrument channel). This test is described in another section of this manual entitled: "Leakage Test Instructions."

1) Inspection of the Insertion Tube

a) Check the entire surface of the insertion tube for abnormal conditions such as dents, wrinkles, or bite marks. Any indentation of the flexible shaft of the fiberscope can cause damage to the internal mechanisms of the fiberscope.

b) Similarly, check the condition of the umbilical cable for outward signs of damage such as buckling, crush marks, etc.

CAUTION:

To avoid further damage to the fiberscope or the possibility of malfunction during a procedure, do not use any fiberscope with outward signs of damage.

c) Make sure that the entire fiberscope is clean and has been subjected to either a high-level disinfection or sterilization process before each patient use.

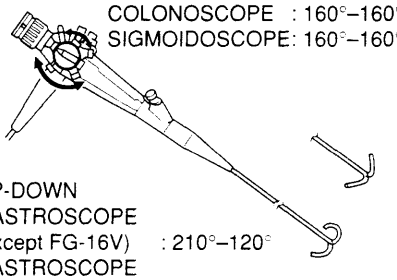
⚠WARNING:

All instruments must be reprocessed prior to first time use, after any repairs/service and before every patient use.

NOTE:

The distal end of the fiberscope must be protected against damage from impact. Never apply excess force such as twisting, or severe bending to the flexible portion of the fiberscope.

RIGHT-LEFT
GASTROSCOPE
(except FG-16V) : 120°–120°
GASTROSCOPE
(FG-16V) : 160°–160°
DUODENOSCOPE: 110°– 90°
COLONOSCOPE : 160°–160°
SIGMOIDOSCOPE: 160°–160°



UP-DOWN
GASTROSCOPE
(except FG-16V) : 210°–120°
GASTROSCOPE
(FG-16V) : 180°–180°
DUODENOSCOPE: 120°– 90°
COLONOSCOPE : 180°–180°
SIGMOIDOSCOPE: 180°–180°

2) Inspection of Deflection Controls and Locks

a) Slowly manipulate the Up/Down and the Right/Left control knobs to see that they function smoothly. Be certain that a full and appropriate range of deflection is possible.

b) Engage the deflection locks to be certain that the position of the deflected tip can be stabilized.

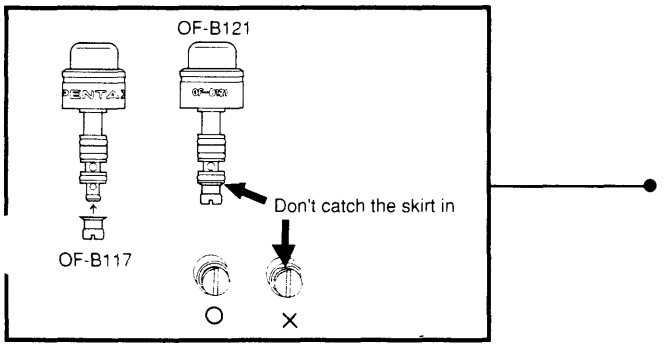
CAUTION:

ANY lack of smooth operation of the deflection controls may be an early indication of internal damage to and/or part(s) failure within the endoscope's angulation system. To avoid the possibility of further endoscope damage or the potential for malfunction of the angulation system, do NOT use the endoscope if the angulation mechanism does not operate properly.

Prior to use ensure that the deflection controls can rotate smoothly, that there is no grinding or excess friction within the angulation system and that the distal bending section bends freely and smoothly. NEVER APPLY EXCESSIVE FORCE TO THE DEFLECTION CONTROLS!

When an endoscope exhibits excessive "knob play" or if angulation is lost in any direction, do NOT use the instrument. Excessive "knob play" can be defined as rotating of the angulation control knob(s) in any one direction for more than 30 degrees without any corresponding distal tip deflection. The examples above are indications that service is requlred to avoid more serlous problems with the angulation control system, including angle or pulley cable/wire breakage and/or the possibility of a "frozen" distal bending section.

A "frozen" bending section can make instrument extraction from a patient more difficult.



3) Inspection of Air/Water Feeding Mechanism

a) Prior to use, the air/water feeding valve (OF-B121) should be inspected. Remove the valve from the control body and make sure that the black rubber check-valve (OB-B117) is properly attached to the bottom of the metal valve stem.

b) If the rubber check-valve is missing or not attached properly, correctly reposition the check-valve by turning it several times on the air/water valve stem. For proper positioning, there should be no clearance (gap) between the rubber check valve and the metal air/water valve stem.

⚠ *WARNING:*

Prior to use, always ensure that a check-valve in good condition is properly attached to the air water valve. A worn or damaged check-valve should be replaced with a new one which has already been subjected to a high-level disinfection or sterilization procedure. For repeated use, always ensure that the check-valve has already been reprocessed.

A damaged, worn or missing check-valve could create continous air flow or excessive air insufflation and result in potential patient injury such as perforation.

If the check-valve is not attached properly, it could fall off during the endoscopic procedure and result in potential injury to the patient.

CAUTION:

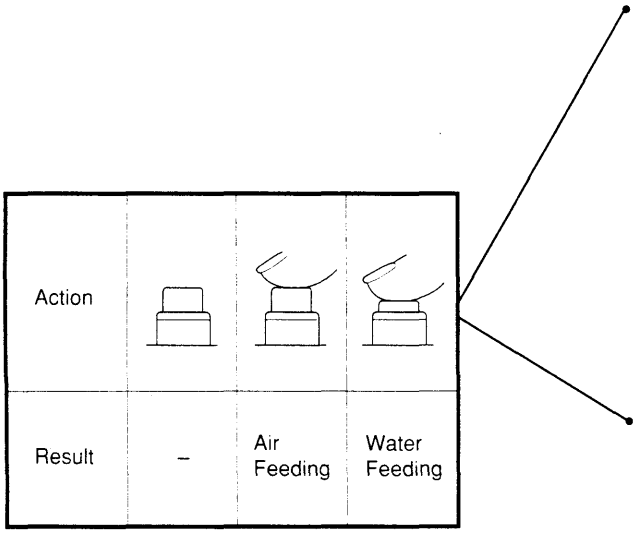
If there is any doubt, replace the check-valve with a new, fully reprocessed one for each procedure. OF-B129 consisting of 20 pieces of OF-B117 is optionally available.

c) To confirm that the check-valve is attached properly, visually inspect the check-valve and install the air/water valve into the air/water cylinder on the control body. Proceed to test the air delivery function.

d) Connect the scope to the light source. Turn air pump "ON" to desired pressure setting.
Place the scope distal tip into sterile water and confirm that no air bubbles exit the distal air nozzle.

> ⚠ *WARNING:*
> *If air bubbles are observed during the test, the rubber check-valve MUST BE REPLACED. Repeat the test procedure with a new check valve (OF-B117).*

e) To inspect air delivery, cover the hole at the top of the air/water valve and confirm that air flows freely from the air/water nozzle at the scope disital tip.

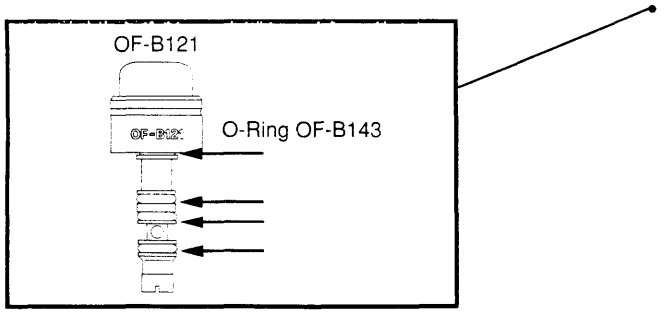


> *NOTE: (**FG-16V GASTROSCOPE only**):*
> *The FG-16V gastroscope incorporates a single internal channel and common nozzle for air and water delivery. Therefore,when air delivery is attempted after water feeding, there will be a slight delay in insufflation while remaining water within the common channel is expelled.*

f) By depressing the air/water feeding valve, the water delivery system is activated. Water should flow in a steady stream from the air/water nozzle at the distal tip of the endoscope. (This may take several seconds on the initial attempt.) USE STERILE WATER ONLY.

g) Release the air/water valve to determine if the valve freely returns to its OFF (neutral) position and delivery of water (and air) ceases.

h) If the air/water valve does not move smoothly, remove the valve and apply a small amount of silicone oil lubricant onto all the O-rings.
Remove/wipe off excessive lubricant with a soft gauze.
Do not use excessive silicone oil.



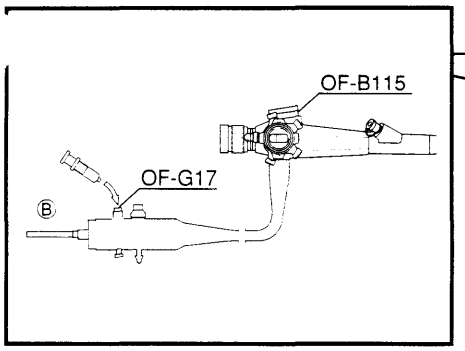
> *NOTE:*
> *Excessive silicone oil (lubricant) should be avoided to prevent occlusion of the internal air or water channels/nozzles and potential impairment of the normally clear endoscopic image.*

> *NOTE:*
> *If air and/or water do not flow properly, NEVER attempt to clear the air or water nozzles with a needle or any other sharp object. Instead, the following steps should be followed:*

(3-1) Disconnect the endoscope from the light source.

(3-2) Remove the air/water feeding valve and the suction control valves.

(3-3) Using a cotton tip applicator and alcohol, clean the valve recess in the control body thoroughly to remove any debris. Do Not attempt to insert the applicator into the small openings within the valve receptacle as the cotton or applicator could become lodged within these openings and cause channel blockage.



(3-4) Clean the air/water feeding valve assembly thoroughly and rinse well.

(3-5) As illustrated, install the adapters (Part #OF-B115 and OF-G17) provided as part of the channel cleaning adapters.

(3-6) The adapter illustrated as Ⓑ in the figure has a luer lock connector to which a syringe should be attached. Alcohol or a compatible enzymatic detergent solution should be flushed through this connection and will flow through both the air and water tubing and nozzles of the endoscope. Soaking of these channels with detergent solution should dissolve and dislodge whatever is restricting the normal delivery of air or water. Fill the syringe with air and flush through the endoscope several times to force any residual solution out of the tubing and nozzles.

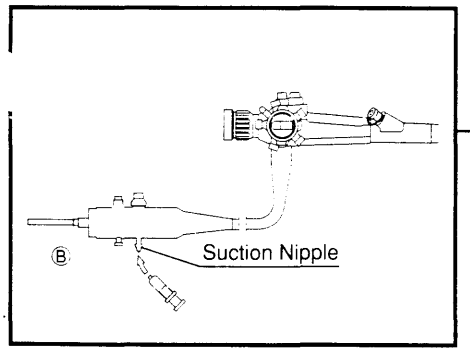
NOTE:

The following alternate method should only be used on a partially occluded air or water channel.

Do NOT use high pressure on a completely clogged channel/nozzle as excessive pressure could result in scope damage.

Part OF-B115 allows simultaneous flushing of both air and water channels. To direct pressurized fluid (or air) separately to each channel, leave the air/water feeding valve attached to the cylinder instead of using OF-B115. Then follow instructions for connecting syringe to adapter (OF-G17) as illustrated in Ⓑ in the figure at left.

Pressure can be directed to the air system by covering the hole in the air/water valve. For flushing of the water line, the air/water valve must be fully depressed with the hole covered.



NOTE:

Thoroughly dry the air and water channels of the scope.

70% alcohol followed by compressed air, not greater than 165 kPa (1.69 kg/cm², 24PSI), may be used to facilitate drying via the OF-G17 adapter.

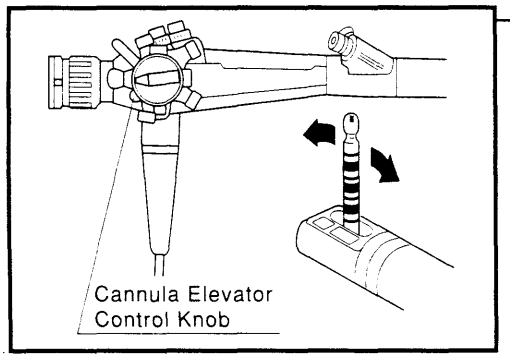
(3-7) Remove the adapters used in step (3-5) and install the air/water feeding valve. Test for normal delivery of air and water. It may be necessary to repeat the procedure outlined in steps (3-5) & (3-6), if normal air and water delivery is still not available.

CAUTION:

If air or water delivery is not functioning properly, do not attempt to use the endoscope on a patient. Contact the PENTAX Service Department.

NOTE:

Prior to clinical use, it is important that the entire air channel be dry. Failure to thoroughly dry the air system could result in an unclear or blurry image caused by very fine droplets of moisture being swept over and/or onto the objective lens at the distal end of the scope.



4) Inspection of Cannula Elevator **(DUODENOSCOPES ONLY)**

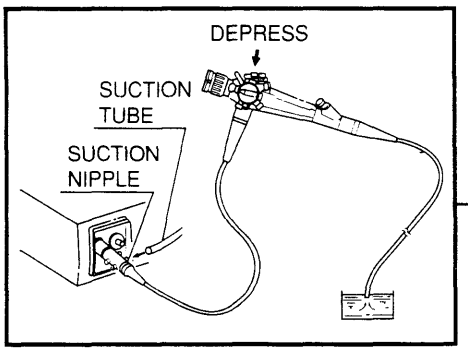
This is the control that will guide and direct either the cannula. biopsy forceps or other accessory during a procedure. To inspect. push cannula elevator control knob forward with thumb of the left hand. The cannula elevator in the distal tip should elevate in proportion to the distance the control knob is moved. The motion of the elevator and the knob should be smooth and easy without any "play" involved.

5) Inspection of Cannula **(DUODENOSCOPES ONLY)**

Make sure a cannula is clean and free from kinks. and the lumen is patent.

⚠WARNING:

Cannulas and other accessories which enter the biliary tract should be sterile.



6) Inspection of Suction Mechanism

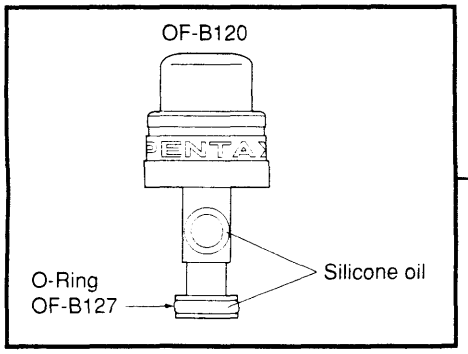
a) Prior to use, the suction control valve (OF-B120) should be inspected. Remove the valve from the control body and make sure that the valve is not damaged.

b) Connect suction tubing from an external suction source to the suction nipple located on the light guide plug at the end of the umbilical cable. Place the distal tip of the endoscope in a basin of water and depress the suction control valve. Water should be rapidly aspirated into the suction system collection container.

c) Release the suction control valve to determine if the valve freely returns to its OFF position and the aspiration of water ceases.

CAUTION:

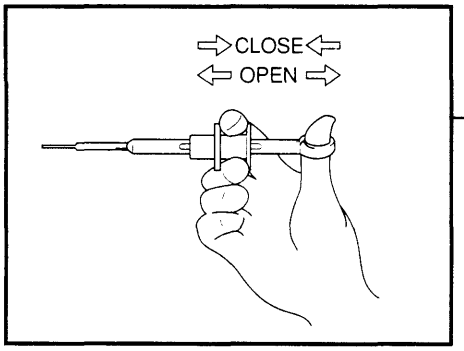
If the instrument is to be used immediately after the inspection, use only "fresh" distilled or sterile water. To avoid recontamination of a previously reprocessed endoscope, avoid use of idle/uncovered tap water.



d) If the suction valve does not move smoothly. remove the valve from the suction cylinder on the control body of the endoscope. Apply a small amount of silicon oil lubricant. OF-Z11. onto all rubber O-rings. Remove/wipe off excess lubricant with a soft gauze. Do not use excessive silicon oil.

NOTE:

Rubber inlet seals in good condition must be on the instrument channel inlet to prevent loss of suction and a risk of cross contamination to the end user due to the potential for reflux (spit-back) of patient fluids. These rubber seals are semi-disposable and should, therefore, be checked before use and replaced as needed. Worn and/or damaged seals may result in leakage and should be replaced. To ensure maximum performance of these sealing mechanisms, consider replacing the rubber inlet seal with a new fully reprocessed one for each procedure.



8) Inspection of Biopsy Forceps and Instrument Channel

a) Make sure there are no kinks in the flexible shaft of the biopsy forceps.

b) The jaws of the forceps must be free of any residual debris. Any debris must be cleaned from the forceps before they are used.

c) The handle mechanism on the forceps should be operated to open and close the jaws. This mechanism should operate freely.

d) Close and inspect the jaws of the forceps to make sure the cups are in proper alignment. If the forceps has a spike, the spike must be completely straight and fully within the cups.

⚠WARNING:

The use of any forceps or accessory that shows any sign of damage or difficulty of operation must be avoided. Any malfunction of a forceps or accessory during a patient procedure could result in serious injury to the patient. Also, the use of damaged forceps or accessories may result in serious and costly damage to the endoscope.

e) Any accessory should be slowly inserted through the instrument channel inlet with the endoscope in a straight position. There should be no resistance encountered. If resistance is encountered, do not attempt to introduce the accessory further, the instrument channel may be damaged and the endoscope should not be used. Contact the Pentax Service Department.

⚠WARNING:

All patient contact accessories must be thoroughly cleaned and subjected to an appropriate high-level disinfection or sterilization process before being used for the first time and subsequently after each clinical use.

CAUTION:

The instrument channel is made of stainless steel, poly phenylene oxide and fluorine-contained polymers.

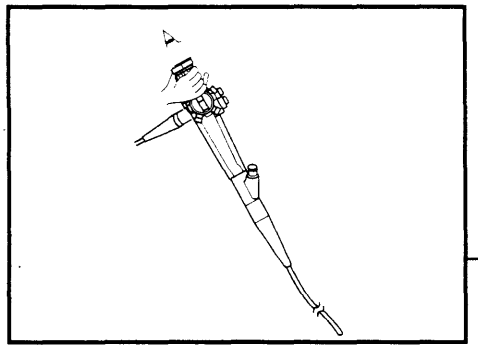
When any fluids are used with this scope, please read carefully and follow all instructions in the manual supplied with the fluids for use and pay special attention to any reactions with the materials identified in the intended fluid path.

Only the user can determine if the fluids are appropriate for patient use.

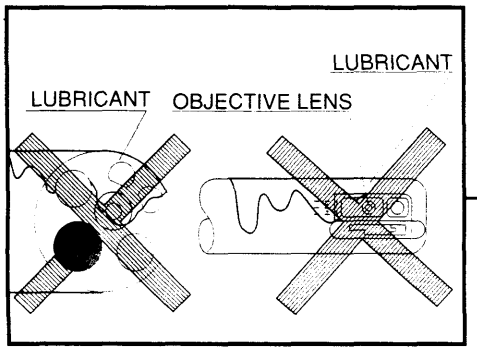
2-3. PREPARATION JUST BEFORE INSERTION OF FIBERSCOPE

> ⚠ *WARNING:*
> *Every fiberscope should be properly disinfected or sterilized before being used for the first time. Every fiberscope should have been properly cleaned, disinfected, or sterilized after any previous use.*

> ⚠ *WARNING:*
> *Current infection control guidelines require that endoscopes and their patient contact accessories either be sterilized or at the least be subjected to high-level disinfection.*
> *Accessories which ENTER STERILE TISSUE or THE VASCULAR SYSTEM must be sterilized before patient use.*
> *It is recommended that any accessory intended for use in the biliary tract be subjected to an appropriate sterilization process.*
> *Only the user can determine if an instrument has undergone appropriate infection control procedures prior to each clinical use.*



1) Check the optical image of the endoscope.
2) If necessary, gently clean the objective lens with a cotton-tip applicator moistened with 70% alcohol. A lens cleaner (anti-fogging agent) may also be applied via gauze or other applicator .
3) The individual user should adjust the diopter adjustment ring to make sure that a clear view can be obtained. No further adjustment should be necesasry during a procedure.
4) **(GASTROSCOPES AND DUODENOSCOPES ONLY)**
   Place a bite block on the insertion tube to protect the insertion tube after the scope is introduced.
5) Apply a medical grade water soluble lubricant to the insertion tube. Do not use petroleum based lubricants.



> *NOTE:*
> *The objective lens must be kept free of the lubricant and excess lens cleaner.*

> ⚠ *WARNING:*
> *Never drop this equipment or subject it to severe impact as it could compromise the functionality and/or safety of the unit. Should this equipment to be mishandled or dropped, do not use it. Return it to an authorized Pentax service facility for inspection or repair.*

3. DIRECTIONS FOR USE

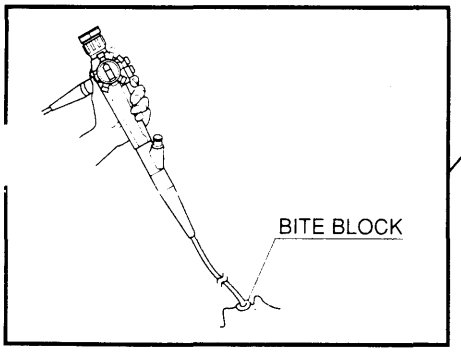
⚠ *WARNING:*

This instrument should only be used by physicians who have thoroughly studied all the characteristics of this instrument and who are familiar with the proper techniques of endoscopy. During the procedure, always wear protective garments such as gloves, gowns and face masks, etc. to minimize the risk of cross contamination.

3-1. PRETREATMENT

1) The patient should be prepared in your normal endoscopy regimen.

3-2. INSERTION AND WITHDRAWAL



1) Slowly insert the scope under direct vision.

2) **(GASTROSCOPES AND DUODENOSCOPES ONLY)**
When the distal end of the scope is passed through the pharynx, the patient should be gently biting down on the bite block to maintain the bite block's position during the procedure.

3) Adjust the intensity of the light source to obtain a brightness level suitable for observation.

NOTE:
The automatic brightness control mode of LX-750P should NOT be used with these scopes since there is no photosensor control circuitry within these instruments.
The risk of thermal injury exists because in the absence of this electrical system, LX-750P, when in the automatic brightness mode, will transmit maximum illumination.

4) The deflection controls should be used as needed to position the scope. The deflection of the tip should be done under direct vision in a gentle and deliberate manner.

CAUTION:
ANY lack of smooth operation of the deflection controls may be an early indication of internal damage to and/or part(s) failure within the endoscope's angulation system. To avoid the potential for malfunction of the angulation system, do NOT use the endoscope if the angulation mechanism does not operate properly.
Ensure that the deflection controls can rotate smoothly, that there is no grinding or excess friction within the angulation system and that the distal bending section bends freely and smoothly.
NEVER APPLY EXCESSIVE FORCE TO THE DEFLECTION CONTROLS!
If during a procedure angulation is lost in any direction such as when "cables snap" (broken pulley wire, broken angle wire, etc.), do NOT continue to use the instrument and do NOT rotate the deflection controls. Should the angulation system fail for any reason, stop the procedure, release the lock lever and carefully withdraw the endoscope under direct visualization.
The examples above are indications that service is required to avoid more serious problems with the angulation control system, including the possibility of a "frozen" distal bending section.
A "frozen" bending section can make instrument extraction from a patient more difficult.

Insufflation can be controlled by the combined use of the air valve (or CO_2 valve) to increase the amount of insufflation and the suction control to decrease the level of insufflation.

6) The user may elect to use CO_2 delivery in lieu of air delivery by using the CO_2 gas adapter (OF-G11)

> ⚠ *WARNING:*
>
> *It must be recognized that variations in air flow (pressure and volume) for patient insufflation may exist from one manufacturer's equipment (light source and/or scope type) to another. It is, therefore, important to closely monitor the patient at all times and to* ***aspirate*** *excessive air to prevent overinsufflation and potential pneumatic perforation.*

7) Mucous or other debris may be aspirated via the instrument channel to improve visualization. Do not attempt to aspirate solid materials.

8) The objective lens may be cleaned during the procedure by alternately using the air/water and suction control valves.

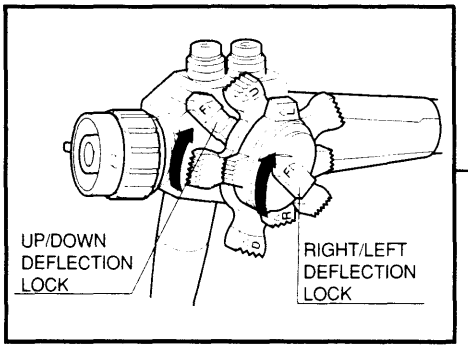
> *NOTE:*
>
> *Should debris on the objective lens be difficult to clean, one can* ***temporarily*** *use the HIGH air pressure setting on the light source and simultaneously press the air/water and suction valves. Return air pressure setting to original selection before proceeding.*

9) Photography may be carried out as necessary.

10) Before withdrawing the scope, trapped air should be suctioned to reduce patient discomfort.

11) When attempting to withdraw the scope, return the deflection lock levers to their free position. Always withdraw the scope under direct visualization.

12) **(GASTROSCOPES AND DUODENO SCOPES ONLY)**
Finally remove the bite block from the patient.

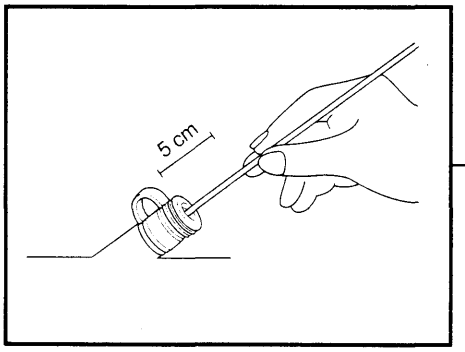


> ⚠ *WARNING:*
>
> *If for any reason, the image is lost due to power shortage, lamp or light source failure, etc. the deflection lock levers should be released, the scope tip should be* ***straightened*** *to its neutral position, and the insertion tube should be carefully and slowly withdrawn from the patient.*

3-3. BIOPSY

CAUTION:

For ALL types of endoscopic accessory instruments, always maintain a view of the accessory during advancement, use and withdrawal of the device.



1) Insert the forceps through the slit in the rubber inlet seal. Be certain to hold the forceps handle in such a way to ensure that the jaws of the forceps are in a fully closed position during insertion.

NOTE:

When the cups are first passed through the inlet seal, a temporary resistance will be encountered. Hold the shaft tightly at about 5cm from the cups and push it through.

NOTE:

During insertion, if the forceps are found hard to advance further due to resistance, decrease the deflection of the bending section to a level suitable for smooth insertion and insert the forceps again.

CAUTION:

Never apply excessive pressure when introducing any accessory since the instrument channel may be damaged. Malfunction of the scope as well as costly repairs may result.

2) When a portion of the cups of the forceps becomes visible in the viewing field, carefully advance the forceps onto the target area.

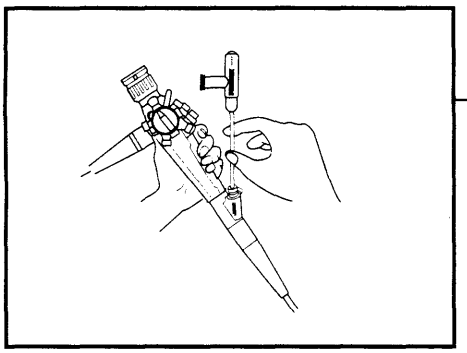
3) Open the forceps cups and advance the forceps against the target area. Carefully squeeze the forceps handle to close the cups and obtain a specimen within the cups. Always maintain a view of the accessory during advancement.

4) Withdraw the forceps slowly with the cups closed.

NOTE:

Because of the effect accessories used in the instrument channel of the fiberscope can have on the performance of the fiberscope itself, it is strongly recommended that PENTAX accessories be used with PENTAX fiberscopes. If a unique or highly specialized accessory is available from another source. please contact PENTAX to arrange a test of its compatibility before using it through the PENTAX fiberscope.

3-4. CHOLANGIOPANCREATOGRAPHY (ERCP) DUODENOSCOPES ONLY



1) Insert the cannula into the biopsy channel through the rubber inlet seal, there could be strong resistance from the inlet at first. Hold the cannula approximately 1cm from the distal tip and push it through the inlet. Use repeated short strokes to advance the cannula.
2) Attach a luer lock syringe filled with contrast material to the cannula. Inject, until air is eliminated from cannula. This will maintain the integrity of the lumen and contrast media while the cannula is in use. EX., if it becomes necessary to use more contrast media or flush with saline.
3) Insert the tip of the cannula into the Ampulla of Vater.
4) Inject contrast material slowly into the duct under visualization.
5) Remove cannula slowly.

NOTE:

Should resistance in passing the cannula be encountered at the distal portion of the scope, gently pull back the cannula, reduce the angle of the cannula elevator, then re-advance the cannula.

CAUTION:

If the cannula elevator is not deflected at all, the cannula may not be seen in the field of view since this is a side viewing instrument. It is recommended that the elevator be slightly deflected so that the cannula exits the distal scope tip and advanced only under full view.

⚠ *WARNING:*

Accessories which ENTER STERILE TISSUE or THE VASCULAR SYSTEM must be sterile. Accessories intended for use in the biliary tract should be sterilized before patient use.

3-5. BILIARY DRAINAGE (ERBD) DUODENOSCOPES ONLY

NOTE:

Endoscopic Retrograde Biliary Drainage should be performed only by those physicians who are completely familiar with endoscopy and ERBD procedure.

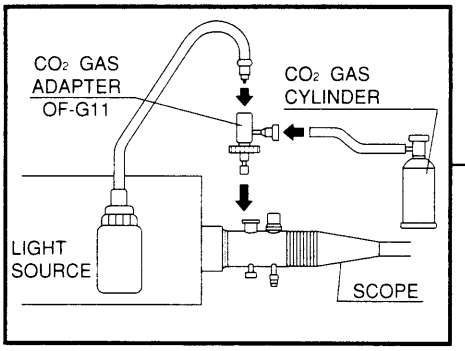
The following is meant solely for the safe passage of catheters and biliary prosthesis through the flexible endoscope. It is not meant to be used as instructions for the procedure itself.

1) Pass the guidewire into the desired location and keep it in position for prosthetic implantation.
2) Thread prosthesis onto the guidewire, then using the pushing catheter, advance prosthesis through the scope and into position.
3) When the prosthetic has been placed in desired position, withdraw the guidewire and pushing catheter.

NOTE:

There are several types of prosthetic devices available, be sure to review the instructions which come with the prosthesis.

2-6. ELECTRO-SURGERY



> ⚠ *WARNING:*
> *Please refer to the operating manual provided with the electro-surgical unit. Electro-surgical systems may be of the floating type (BF type, CF-type) or non-floating (B-type).*
> *To avoid patient and user burn, use only the floating type ESU (such as ERBOTOM ICC 200)/accessory systems. Do not use the non-floating (B type) electro-surgical systems.*
> *The electro-surgical generator and any electro-surgical accessory should be carefully and thoroughly inspected. Only the user can determine if the conditon of the electro-surgical generator and the electro-surgical accessory are suitable.*

1) The user has the option of using a non-explosive gas for insufflation. Non-explosive gas from a pressure-regulated and flow-rate controlled source can be connected to the provided or optionally available gas adapter, Model OF-G11, as illustrated.

> *NOTE:*
> *Never connect an unregulated source of gas to the PENTAX fiberscope.*

2) The gas adapter, which can be secured to the air/water connector on the L.G. Plug, has a luer receptacle to accept tubing from an external source of non-explosive gas. As long as the air/water feeding tube from a PENTAX water bottle assembly is connected to the gas adapter and the air pump in the light source is turned OFF, non-explosive gas and water can be delivered.

> *NOTE:*
> *Set the pressure below 49 kPa (0.5kg/cm² 7.1PSI), and the flow rate at about 1 liter/min.*

> *CAUTION:*
> *Open the valve of the CO_2 gas cylinder only AFTER turning off the light source pump switch. Failure to do so will apply excessive pressure to the light source and can cause damage to the air pump.*

3) Flow of gas from the nozzle at the distal end of the scope can be checked by placing the tip of the scope under water and covering the hole on the top of the air/water valve. The flow rate of gas should be no greater than the rate of air delivery when the air feeding valve on the control head of the scope is coverd.
4) The water delivery system is activated by depressing of the air/water feeding valve.
5) The rubber eye shield should be used on the eyepiece of the endoscope and the operator and assistant(s) should also wear surgical gloves to avoid burns during use of electo-surgical devices.
6) The electro-surgical accessories should be introduced through the fiberscope in the same manner as described for biopsy forceps in section 3-3.

NOTE:

It should be noted that as long as the valve of the CO_2 gas cylinder is OPEN and the hole at the top of the A/W feeding valve is NOT covered, CO_2 gas will constantly be vented through the A/W valve into the room. To reduce excessive CO_2 concentrations, it is, therefore, recommended to close the CO_2 gas cylinder valve, work in a well ventilated room, and use air delivery whenever possible during examinations which are lengthy or in very confined quarters.

As an alternative, the optionally available gas/water valve, Model OF-B130, may be used in place of the standard air/water valve. OF-B130 is a closed two-stage valve mechanism. Pressing the first stage delivers CO_2 gas and fully depressing the second stage activates water delivery.

When using the OF-B130 valve, there will be no venting of CO_2 gas into the room.

Replace OF-B130 with the air/water valve OF-B121 after using the CO_2 gas.

NOTE:

One may choose to leave the OF-G11 adapter attached to the endoscope during conventional air insufflation using the standard air/water valve (OF-B121). However, the luer sideport of the OF-G11 must be capped.

Similarly, for normal water delivery, the air pump must be turned ON and the plastic luer lock cap must be secured to the OF-G11 adapter.

⚠ *WARNING:*

To avoid patient and user burn, follow the instruction below before electro-surgical-energy is delivered.

1) *Use only the electro-surgical generator with the floating grounding type (BF or CF Type). Do not use the non-floating (B type) electro-surgical systems.*
2) *Wear rubber gloves, face masks and place a rubber eyeshield on the eyepiece of a fiberscopes.*
3) *The position of the target area, the insulated distal portion of the electrosurgical accessory and the active portion of the electrosurgical accessory, should be visible.*
4) *The active portion of the electrosurgical accessory should not touch the metallic distal portion of the endoscope directly or via fluids.*
5) *The metallic portion of the endoscope should not touch the surrounding tissue directly or via fluids.*
6) *The active portion of the electrosurgical accessory should not touch the surrounding tissue directly or via fluids during delivery of electrosurgical (high-frequency) energy.*
7) *Physicians and assisting personnel should avoid contact with the patient while high frequency energy is delivered.*
8) *Electro-surgical energy should be delivered for as short a time period as necessary to accomplish the desired clinical effect.*
9) *The head of any lesion such as polyp should not touch the surrounding tissue directly or via fluids.*
10) *Select a high frequency output power setting suitable for the particular intended procedure in order to avoid thermal invasion of the tissue, which can be caused by too low a setting, or insufficient coagulation, resulting in excessive bleeding, which can be caused by too high a setting.*
11) *To avoid the risk of thermal injury, use only insulated accessories.*

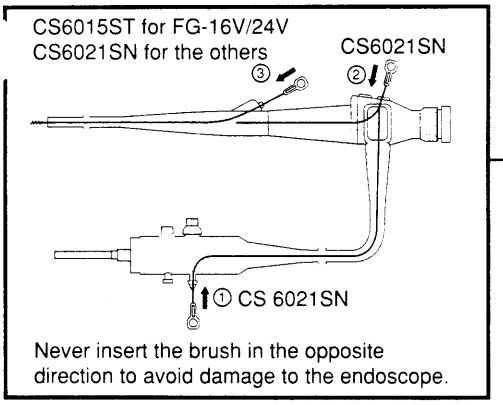
Never use non-insulated devices while performing endoscopic electro-surgical procedures.

NOTE:

Depending upon the brand and/or type of electrosurgical unit, a scope feedback cord must be connected between the endoscope's feedback terminal and the electro surgical generator.

This scope feedback system allows for return of current leaked to the endoscope back to the patient line of the electro-surgical generator which, in a floating ground system, is isolated from the main ground.

This, thereby minimizes the leakage currents between patient, operator and/or assistant(s) to the main ground resulting in a higher level of safety.



Never insert the brush in the opposite direction to avoid damage to the endoscope.

NOTE:

Do not squeeze or severely bend the insertion tube. Do not use any abrasive materials. Be careful to avoid damage to the distal lenses.

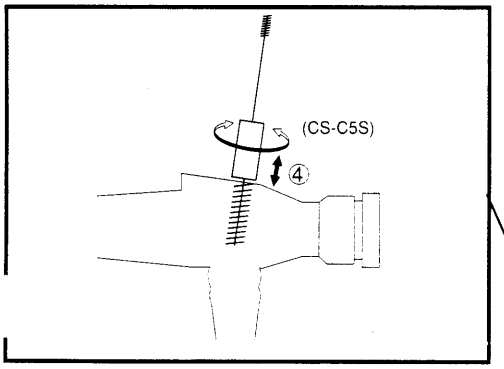
4) **Manual Cleaning by Brush**

A variety of special brushes have been provided to mechanically brush clean the entire suction/instrument channels and tubes. Whenever possible, the entire endoscope should be immersed in detergent solution during the remainder of the cleaning procedure.

Brush clean the entire instrument/suction channel system:

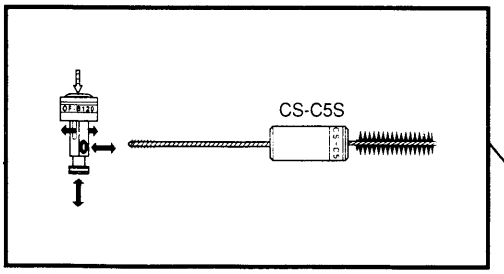
a) Using the cleaning brush provided, insert the brush into the opening of the suction nipple and gently pass the brush until it appears in the suction control valve receptacle. (See ① in figure) This will clean the suction tube within the light guide/umbilical cable. Then gently withdraw the brush. Repeat several times.

b) Next, insert the brush into the opening at the bottom of the suction control valve receptacle (cylinder) on the control head and gently advance until resistance is felt (approximately 15cm). (See ② in figure) DO NOT USE EXCESS FORCE.
Then gently withdraw the brush. Repeat several times until the brush is visibly clean.



NOTE:

Be sure to inspect the bottom of the suction control valve receptacle on the control head for any debris.

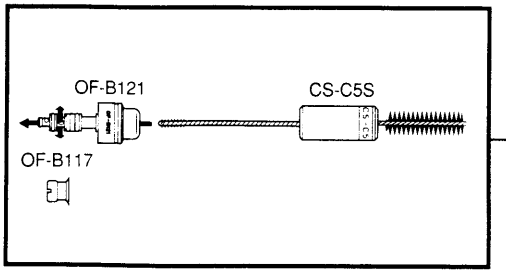


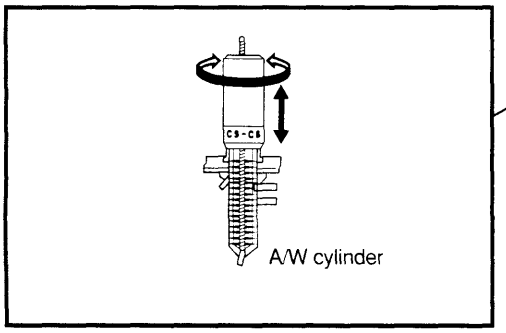
c) Insert the brush into the instrument channel inlet and gently advance the brush until it exits the distal end of the scope. Clean debris off the brush and then gently withdraw the brush. (See ③ in figure). Repeat several times ensuring that only a clean brush is introduced into the channel each time.

d) Using the large bristle of the specially designed cleaning brush (CS-C5S), scrub clean the surfaces inside the suction control valve receptacle on the control head. (See ④ in figure at left)
Do not insert the brush excessively.

e) Scrub all internal and external surfaces of the suction valve (OF-B120) using the smaller side of the cleaning brush (CS-C5S).

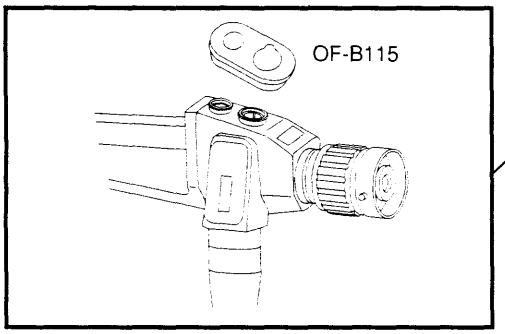
f) Remove the rubber check-valve (OF-B117) from the air/water feeding valve (OF-B121). Scrub all internal and external surfaces of the valve using the smaller side of the cleaning brush (CS-C5S).





g) Using the larger end of the CS-C5S cleaning brush, scrub clean the surfaces inside the air/water cylinder.

NOTE:
Brushing of all internal channels is not a substitute for exposure to an appropriate cleaning solution. Manual cleaning by brush complements and augments the cleaning effectiveness of chemical cleaning (i.e. enzymatic detergent).



5) **Chemical Cleaning by Detergent Solution**

The rubber A/W Instrument channel cleaning adapter (OF-B115) should be attached to the air/water and suction cylinders. This adapter caps (seals) off the air/water and suction cylinders to allow unidirectional flow of solution through these delivery/aspiration systems. Please note that the symbols on OF-B115 show a full circle (◯) and circle with notch (◯) which represent the shape of the respective cylinders for proper attachment. The notched symbol should align with the suction cylinder and the circle symbol, the air/water cylinder.

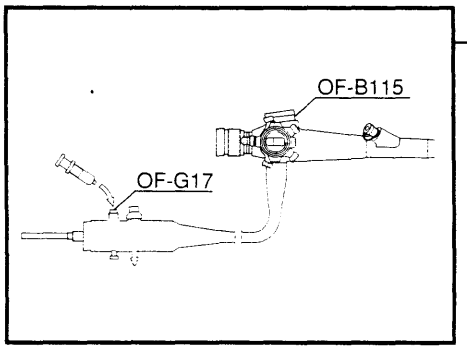
NOTE:
It is imperative that the OF-B115 channel cleaning adapter be securely attached to their respective valve cylinders. Failure to properly match and secure the cleaning adapter could result in ineffective and incomplete reprocessing.

a) **For Air/Water Cleaning**

Air/water channel cleaning adapter, model OF-G17, has a standard ANSI luer lock connector to which a syringe or other device should be attached. Connect OF-G17 to the air/water port on the light guide plug. Fresh detergent should be flushed through this connector and will simultaneously flow through both the air and water channels and nozeles within the scope.

Please refer to the internal schematics.

Provided the enzymatic detergent is allowed remain in contact with the internal channel surfaces for the recommended exposure time, the enzymatic solution should dissolve and clean any remaining debris within these channels.



b) **For Biopsy/Suction Cleaning**

Install a rubber inlet seal to the instrument channel inlet prior to injecting cleaning solution into the suction system.

The suction nipple located on the light guide plug has a standard luer slip fitting to which a syringe (or other device) may be attached. Fresh detergent solution should be flushed through the entire instrument/suction system. The rubber inlet seal should be in place. (Please refer to the internal schematics.)

NOTE:
If blockage of the line is encountered, avoid use of excessive pressure to prevent scope damage.

As an alternative, solution can be drawn into the instrument channel by attaching tubing from an aspirator to the suction nipple, as long as the aspirator is turned on, detergent solution can be suctioned through the scope.

1. CARE AFTER USE

IMPORTANT INSTRUCTIONS

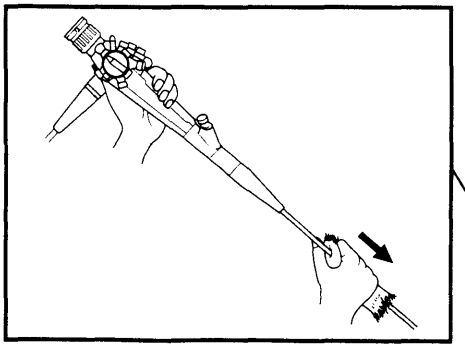
Cleaning-Disinfection-Sterilization: PENTAX Endoscopes

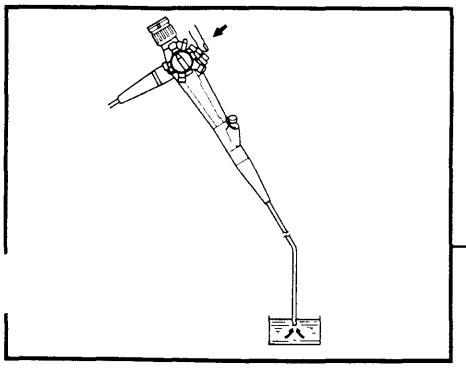
To maintain maximum performance and a long service life of the fiberscope, proper care after each procedure is extremely important. Immediately after the completion of a procedure, the fiberscope should be thoroughly and carefully cleaned. If the fiberscope is left uncleaned for some time after use, dried blood, mucous, contrast material or other debris may cause damage to the instrument or may interfere with the ability of the user to properly reprocess the endoscope.

NOTE: This owner's manual contains detailed recommendations on the manual reprocessing of Pentax endoscopes using Pentax supplied cleaning/disinfecting adapters. Automated endoscope reprocessors (AER) may provide a means of reprocessing flexible endoscopes, including Pentax instruments. However, only those Automated Endoscope Reprocessors (AERs) should be used whose manufacturers provide device-specific instructions and have validation data that support each AER claim with respect to Pentax model instruments.
AER manufacturers should be consulted for their specific claims including but not necessarily limited to

- *(a) the ability of the AER to provide a cleaned and high-level disinfected (or sterilized) endoscope and scope components (ex. valves),*
- *(b) the identification of any special feature area (internal channel) or scope component that can not be reprocessed and therefore requires manual reprocessing,*
- *(c) the microbial quality of the rinse water,*
- *(d) the inclusion of an "automated" alcohol rinse cycle,*
- *(e) the inclusion of a terminal drying cycle that removes the majority of water/fluid within scope channels,*
- *(f) maintenance procedures for water filter replacement and/or decontamination of the filtration system to ensure the microbial claim of water, etc.*
- *(g) compliance with local regulations and/or guidelines*

·1. CARE AFTER EACH PROCEDURE



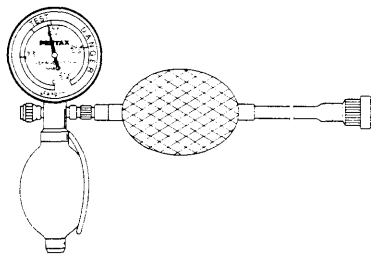


⚠ *WARNING: The importance of meticulous mechanical cleaning of the endoscope and its removable components cannot be overemphasized.*
Prior to disinfection or sterilization, all instruments and components must be scrupulously cleaned.
Failure to do so could result in incomplete or ineffective disinfection and sterilization.
During the reprocessing process, always wear protective garments such as gloves, gowns, face masks, etc. to minimize the risk of cross contamination.

4-1-1 PRE-CLEANING AT THE EXAMINATION ROOM

⚠ *WARNING: Immediately after use, the metal light guide prong of the endoscope may be HOT.*
To avoid bums, do not touch this areas immediately after use.
For safer handling after a procedure, grasp the plastic light guide plug.

1) Immediately after removing the fiberscope from the patient, gently wipe all debris from the insertion tube with a gauze or the like moistened with an enzymatic detergent solution.
2) Place the distal end of the fiberscope into detergent solution and aspirate through the channel for 5~10 seconds. Alternate aspiration of solution and air serveral times to create agitation for better pre-cleaning.



Leakage Tester

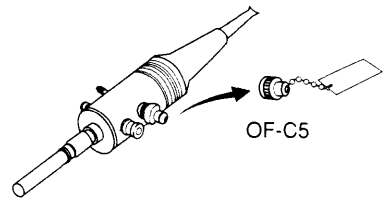
3) Set the lever on the water bottle to the drain position. With the air pump of the light source turned ON and set to the HIGHEST pressure setting, depress the air/water valve of the scope fully until all water has been discharged from the scope. Alternate covering of the hole in the valve and depressing the valve to forcefully expel mucous, debris, etc. which may have entered the air and water nozzles.

4) Place removable scope components in enzymatic detergent solution to pre-soak.

4-1-2 CLEANING AT THE WORK ROOM

1) Before proceeding with any further cleaning steps, the fiberscope should be Leak Tested. See section on Leakage Tester Instructions.
The hand operated PENTAX Leakage Tester is available as an optional accessory.

2) Prepare a basin with warm water and a mild enzymatic detergent per detergent manufacturer's instructions.
The solutions must be enzymatic detergents or other cleaning agents specially formulated to clean flexible endoscopes. For specific brands of compatible solutions, please contact your local Pentax service facility or sales representative.

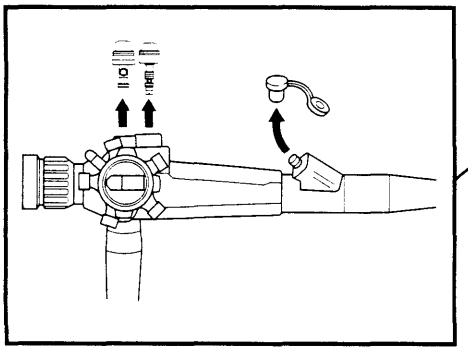


OF-C5

CAUTION:
BEFORE IMMERSING:
The 'Red' ETO gas sterilization venting cap must be taken OFF.

⚠ WARNING:
Immediately after use, the metal light guide prong and the electrical contacts/pins of the endoscope may be HOT.
To avoid burns, do not touch these areas immediately after use. For safer handling after a procedure, grasp the plastic light guide plug.

CAUTION:
The use of an enzymatic detergent immediately after each procedure to dissolve and remove organic contaminants and proteinaceous debris is essential to the care and maintenance of the endoscope from the standpoints of infection control and functionality.



3) Immerse the endoscope and its components in fresh detergent solution. After removing the suction control valve, air/water feeding valve, the rubber inlet seal, etc. thoroughly (but gently) wash the entire surface of the endoscope and its components. Make sure that the recessed areas such as the scope distal tip, channel openings, valve cylinders, etc. are brushed clean using the provided or similarly effective cleaning brushes.

CAUTION:
While fully immersed, manipulate valve mechanisms and inject detergent via syringe into/through removable scope components. This will remove entrapped air bubbles that could inhibit contact of solution with component surfaces & provide for better exposure of surfaces to detergent.

4) Allow all items to soak in an enzymatic solution for a time period recommended by the manufacturer of the enzymatic detergent.

> ⚠ *WARNING:*
> *The enzymatic detergent solution should remain in contact with ALL internal channels and external scope surfaces for the time period recommended by the manufacturer of the detergent.*

6) Prior to rinsing, purge all internal channels with air (using a syringe) to expel residual detergent solution out from each channel.

> ⚠ *WARNING:*
> *It is important that ALL internal channels (air, water, instrument, etc.), external scope surfaces and components be thoroughly rinsed with clean water to remove residual detergent solution.*

7) Using clean water, immerse the entire endoscope as well as all removed components and thoroughly rinse all items.
8) With all cleaning adapters, still attached to the endoscope, flush all previously air purged channels with 200mL clean water. All internal channels must be thoroughly rinsed to remove residual detergent and debris.
9) Rinse water remaining within the channels should be purged using air to prevent dilution and/or adulteration of antimicrobial agents to be used in the subsequent disinfection or sterilization process.

> *NOTE:*
> *70% alcohol followed by compressed air, not greater than 165kPa (1.69 kg/cm², 24PSI), may be used to facilitate drying.*

10) Gently dry all external sufaces of the endoscope with a soft gauze or the like. Do not put tension on the insertion tube on the endoscope while drying since the outer cover of the bending section may be excessively stretched. Dry the objective lens with a cotton tip applicator.

> ⚠ *WARNING:*
> *Prior to disinfection of sterilization, it is imperative that any solutions previously used in the cleaning process be thoroughly rinsed and dried. Failure to do so, could result in ineffective or incomplete disinfection and sterilization.*

> *CAUTION:*
> *Never subject the endoscope to ultrasonic cleaning methods employing high-frequency ultrasound.*

4-1-3 CLEANING OF ACCESSORIES

CAUTION:

Not all manufacturers of automated endoscope reprocessors (AERs) make specific claims nor provide special instructions for reprocessing all of the removable scope components that are integral to the safe and effective operation of flexible endoscopes. Therefore, should the AER manufacturer's instructions not specifically address reprocessing of any particular scope component (air/water valve, suction valve, irrigation valve, inlet seal, irrigation tube, check-valve, selector mechanism, etc.) in the AER, then those components must be reprocessed manually as described in Pentax instructions/labeling. Prior to use, check with each AER manufacturer as to their specific claims with respect to reprocessing individual endoscope components.

1) Reusable accessories such as forceps should be cleaned immediately after each use since dried blood, mucous, contrast material or other debris may cause damage to the instrument and render the mechanism inoperable, or may interfere with the ability of the user to reprocess the device.
2) Place the accessory in a basin with warm water and a mild enzymatic detergent being careful not to tightly coil or kink the flexible wire/shaft.
3) Clean the handle and flexible shaft by gently wiping with a soft gauze or the like. The biopsy cups and pivot pin area should be carefully and gently cleaned with a soft brush. Removal components such as air/water, suction valve, etc. should be manipulated and detergent injected directly into/onto components surfaces.
4) Rinse all residual detergent from the forceps by immersing the entire forceps under clean water and manipulating the handle and cup mechanism.
5) Ultrasonic cleaning of accessories is then recommended, provided the manufacturer's instructions and the parameters below are followed:

Frequency Range	44 kHz ± 6%
Time	5 minutes

DO NOT use caustic or abrasive solutions in the ultrasonic cleaner.

CAUTION:

DO NOT use ultrasonic cleaning methods with high-frequency ultrasound on the fiberscope itself.

NOTE:

It is imperative that ultrasonic cleaning of the accessory be performed PRIOR to autoclaving. Only those PENTAX accessories identified by their pink coloured handle or labeled as being autoclavable may be subjected to steam autoclaving.

NOTE:

All detergent must be removed from the surface of the accessory. Detergent that remains after the water evaporates may cause increased friction that may render the some devices inoperable. Residual detergent may also interfere in the subsequent sterilization process.

6) After cleaning and thorough rinsing, the accessory should be gently dried using a soft gauze or the like. Avoid tight coiling or kinking and do not put tension on the flexible shaft of the accessory.

NOTE:

Other reusable accessories (channel cleaning adapters, cleaning brushes, bite block, etc.) and scope components (rubber inlet seals, air/water and suction control valves, etc.) should be cleaned in a similar manner as above.

Ultrasonic cleaning methods are recommended for accessories and scope components whose entire surfaces are not easily accessible by manual cleaning.

NOTE:

The following endoscopic accessory instruments and scope components may be subjected to ultrasonic cleaning methods:

- *PENTAX biopsy forceps with pink handle*
- *PENTAX cleaning brushes for instrument channel*
- *PENTAX cleaning brush for A/W suction valve cylinder*
- *PENTAX bite block OF-Z5*
- *PENTAX water bottle OS-H4*
- *PENTAX cannula TG1918S*
- *PENTAX suction valve OF-B120*
- *PENTAX A/W feeding valve OF-B121*
- *PENTAX A/W instrument channel cleaning adapter OF-B115*
- *PENTAX check-valve OF-B117*

4-1-4 INTERNAL CHANNELS OF A PENTAX ENDOSCOPE

The following internal schematics have been provided as a service to help users better understand the intricate construction of Pentax endoscopes. Knowledge of the various internal channels and tubes within an instrument and their relation to each other allows one to care for and reprocess the endoscope more easily and with greater confidence.

Much time and effort has been expended into designing endoscopes and their cleaning/disinfecting components so that reprocessing of the instruments before each patient use can be effectively and efficiently performed by either manual methods or automated processes.

Connectors on all Pentax cleaning/disinfecting adapters and scope inlet ports incorporate standard size luer-lock and/or luer-slip fittings to easily accommodate reprocessing devices or systems available from other manufacturers.

As can be seen from the internal schematics, the Pentax cleaning system promotes efficient unidirectional flow of solution beginning from connections at the light guide plug, traveling up tubings in the umbilical cable to the valve cylinders in the control body, passing through the channels in the insertion tube and finally exiting nozzles or channel openings at the distal tip of the scope.

The elimination of multiple branching of channels, combined with a direct and straightforward pathway for solutions to travel maximizes flow efficiency and ensures contact of disinfectant/sterilant with all internally exposed channel surfaces.

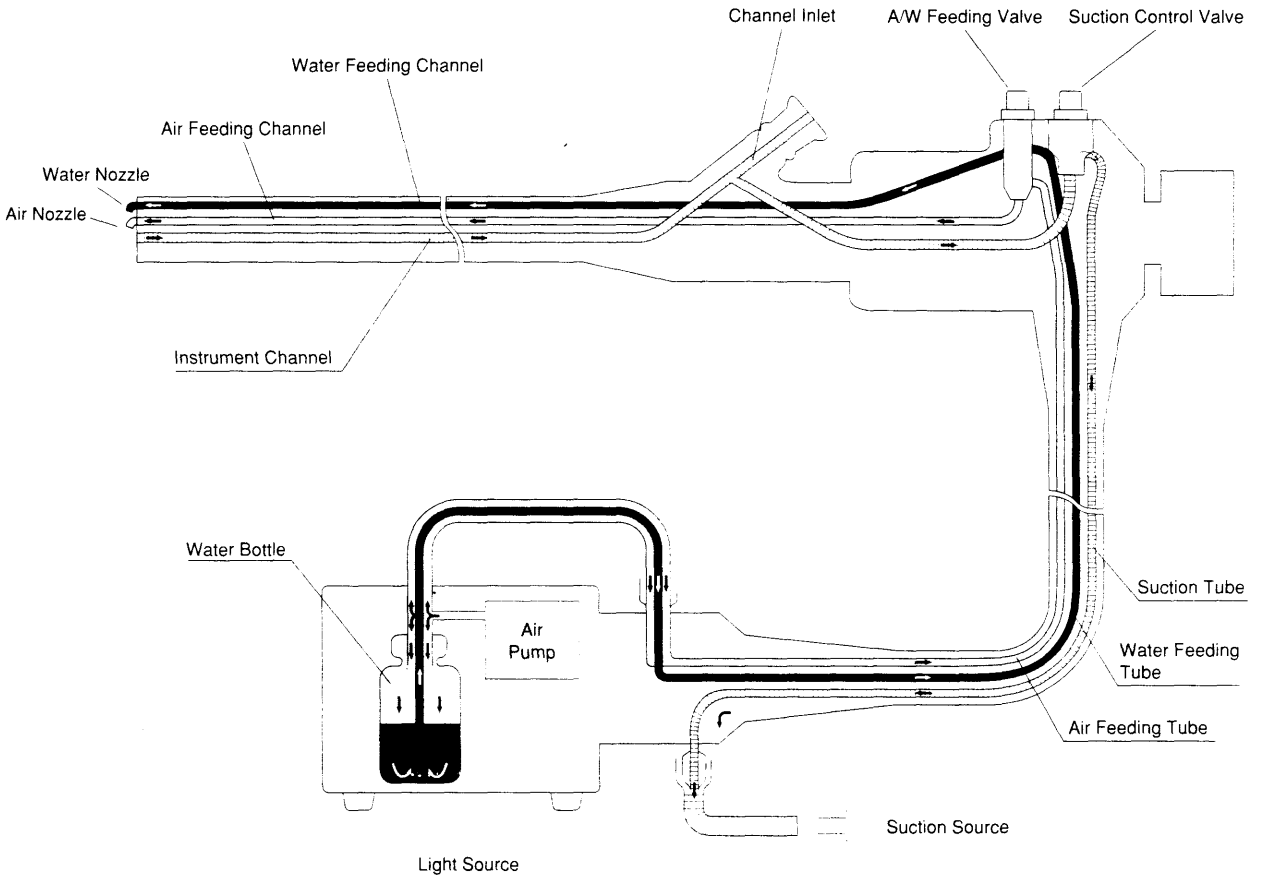
⚠ *WARNING:*

It is imperative that flexible endoscopes and other semi-critical devices be reprocessed using at least high-level disinfection with a legally marketed sterilant/disinfectant. Only legally marketed endoscope automated reprocessing devices/systems whose device specific claims have been validated by the AER manufacturer and/or anti-microbial agents which have been tested and found to be compatible by Pentax should be used with Pentax products.

Generally speaking, "2%" and "3.2%" alkaline glutaraldehyde solutions which have been FDA cleared with High-Level Disinfection and/or Sterilization claims are recommended. It should be noted that the actual percentage of active ingredient (glutaraldehyde) in these solutions, as per their product label, may vary from the generic and traditional terms "2% glutaraldehyde" and/or "3.2% glutaraldehyde"

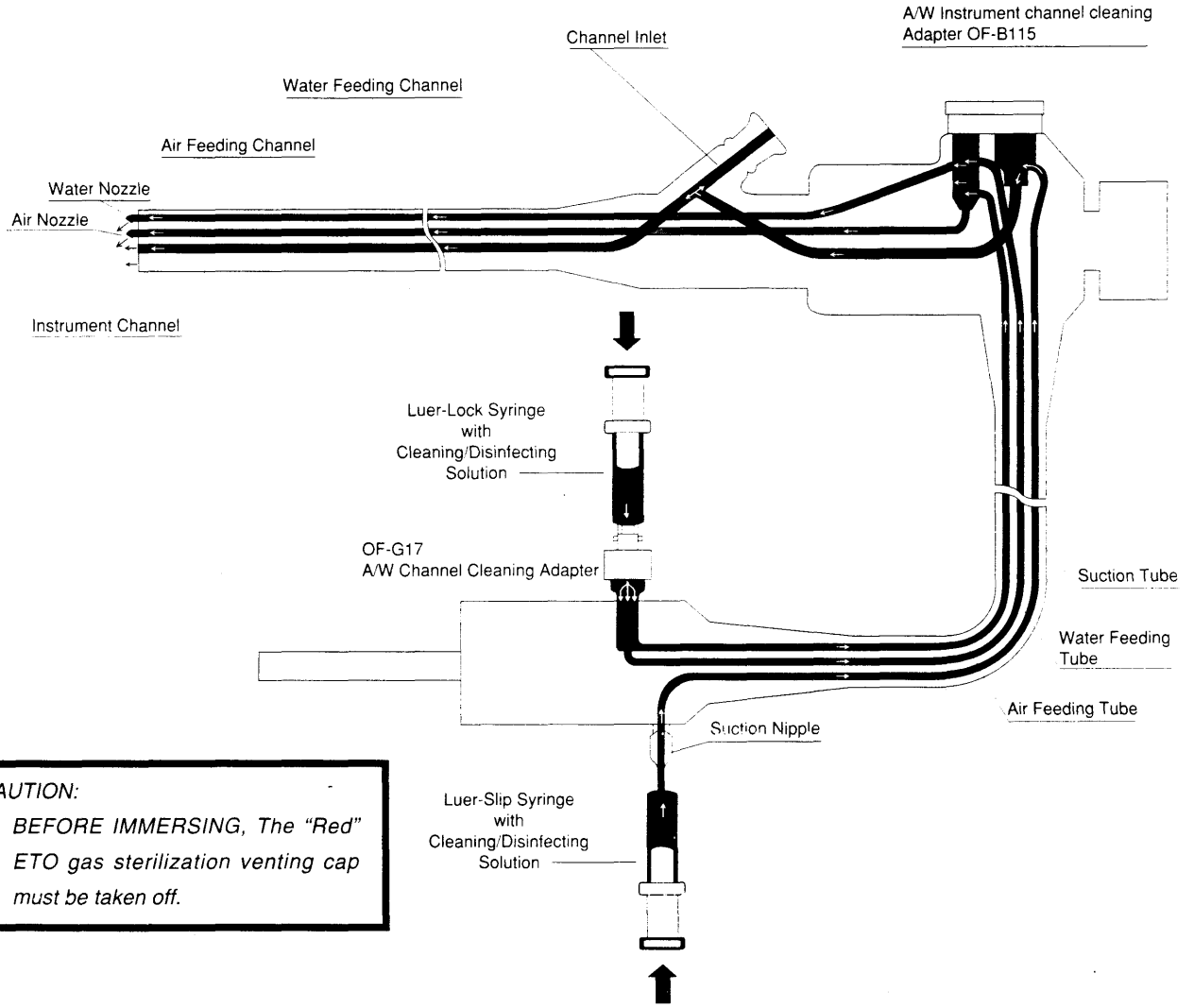
For specific brands of compatible disinfectants/sterilants, please contact your local Pentax service facility or sales representative. Please also refer to the inside front cover of this manual regarding infection control.

INTERNAL CHANNELS OF PENTAX GASTROSCOPE (except FG-16V), COLONOSCOPE AND SIGMOIDOSCOPE



The illustration above shows the actual routes taken by air, water and suction through a Pentax **GASTROSCOPE (except FG-16V), COLONOSCOPE AND SIGMOIDOSCOPE.** Please note that all delivery systems have separate independent channels, all of which must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

INTERNAL CHANNELS OF PENTAX GASTROSCOPE (except FG-16V), COLONOSCOPE AND SIGMOIDOSCOPE SHOWING COMPLETE PENTAX CLEANING/DISINFECTING SYSTEM



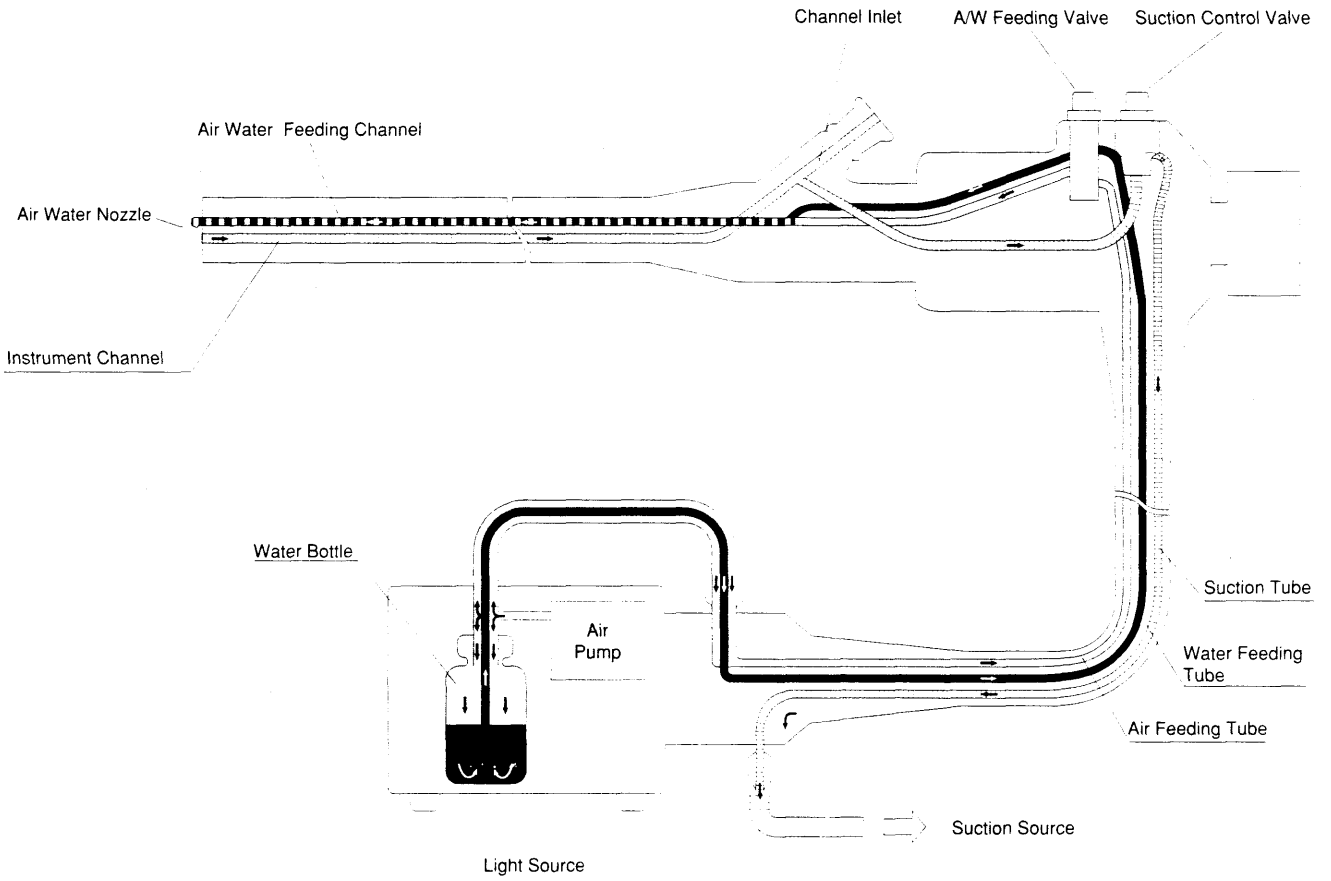
CAUTION:
BEFORE IMMERSING, The "Red" ETO gas sterilization venting cap must be taken off.

To reprocess a Pentax Endoscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be exposed to all internal lumens as well as to all external instrument surfaces and scope components (air/water valve, suction valve, etc.).
Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

Please note that all solution entrance ports and flow pathways are illustrated above.

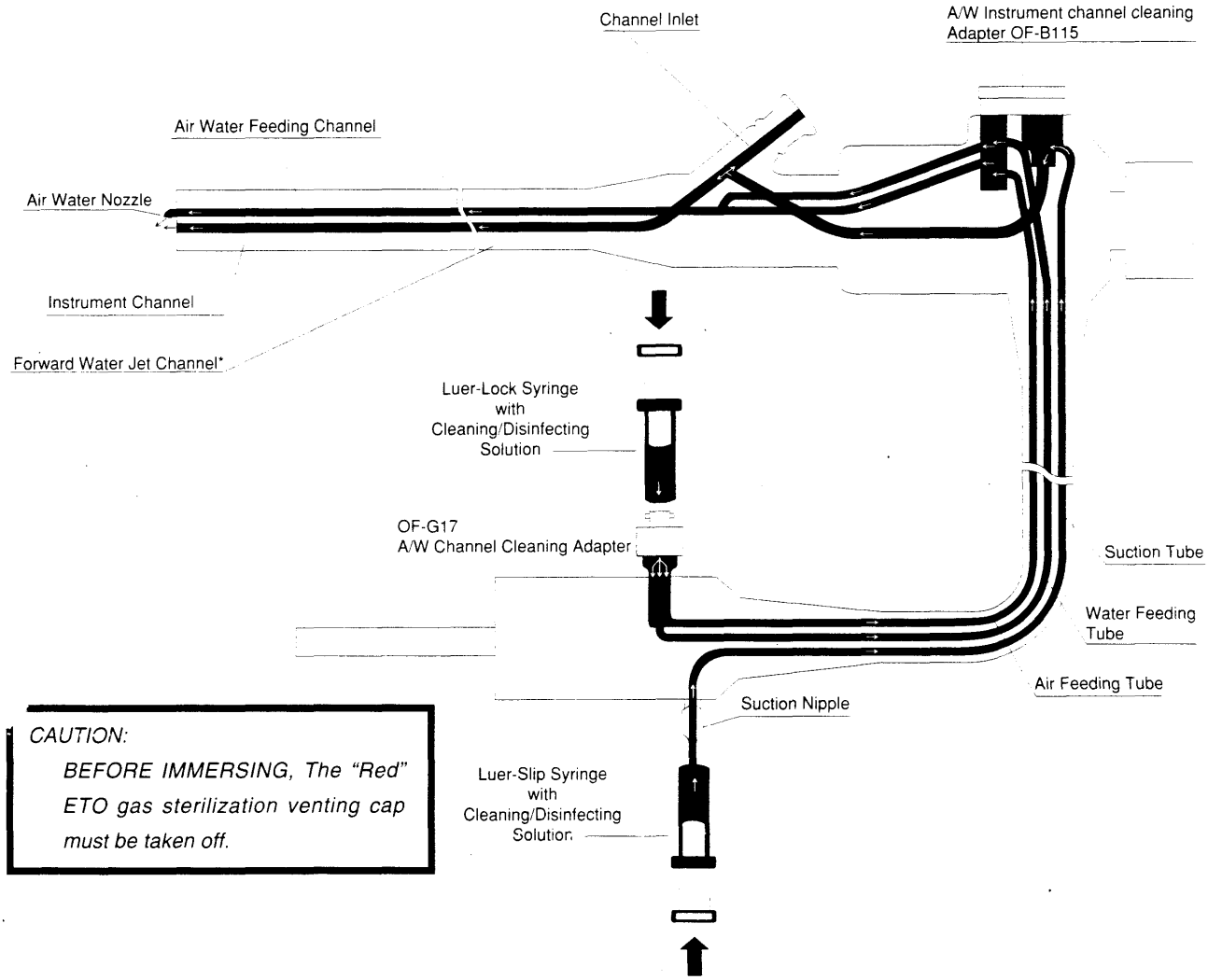
NOTE:
Prior to exposure of all internal channels to an enzymatic detergent and high-level disinfectant (or sterilant) , Pentax channels should be manually cleaned with cleaning brushes.

INTERNAL CHANNELS OF PENTAX GASTROSCOPE FG-16V



The illustration above shows the actual routes taken by air, water and suction through a Pentax **GASTROSCOPE FG-16V.** Please note that all delivery systems must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

INTERNAL CHANNELS OF PENTAX GASTROSCOPE FG-16V
SHOWING COMPLETE PENTAX CLEANING/DISINFECTING SYSTEM

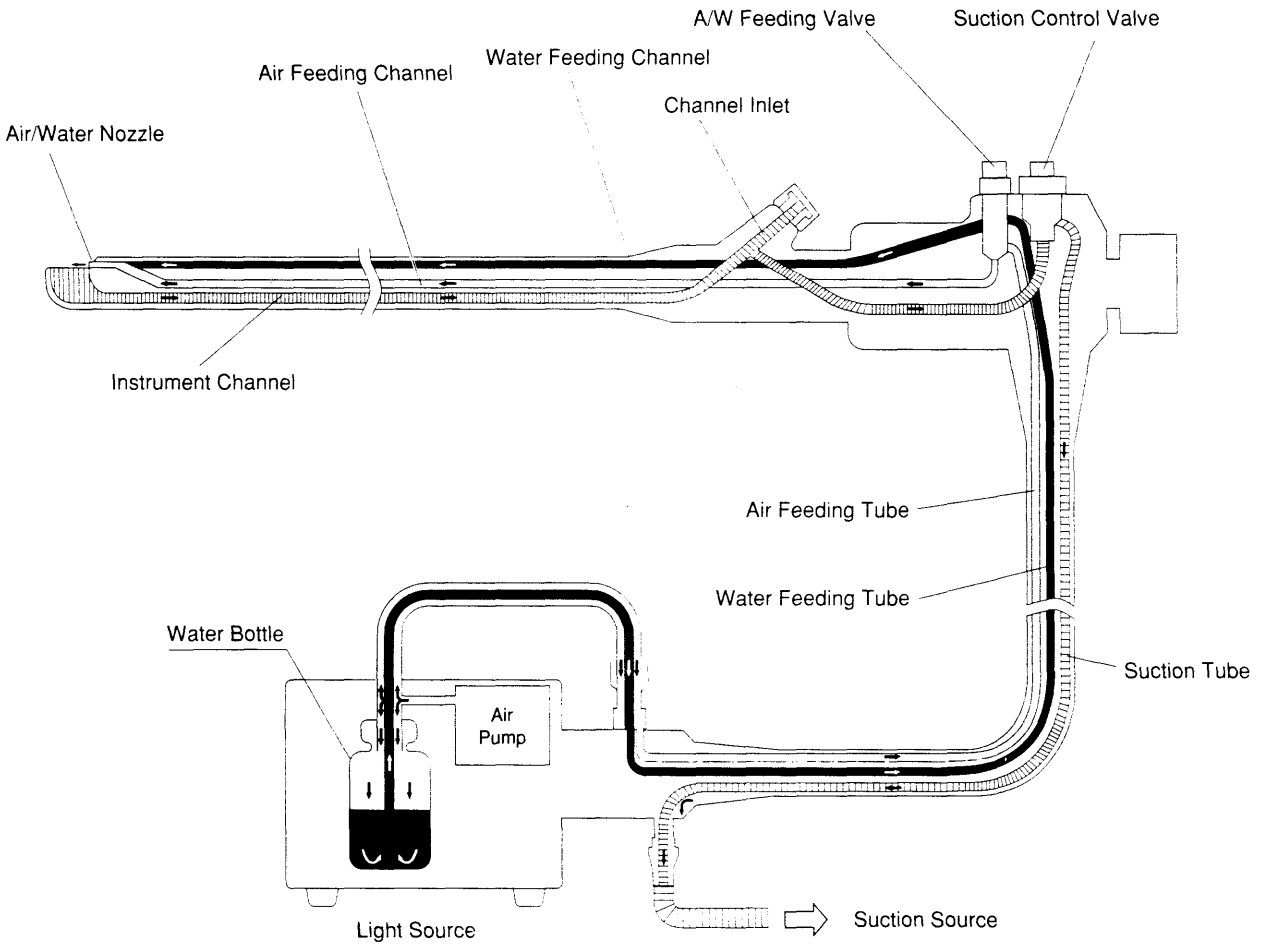


To reprocess a Pentax Endoscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be exposed to all internal lumens as well as to all external instrument surfaces and scope components (air/water valve, suction valve, etc.).
Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

Please note that all solution entrance ports and flow pathways are illustrated above.

NOTE:
Prior to exposure of all internal channels to an enzymatic detergent and high-level disinfectant (or sterilant) , Pentax channels should be manually cleaned with cleaning brushes.

INTERNAL CHANNELS OF A PENTAX DUODENOSCOPE



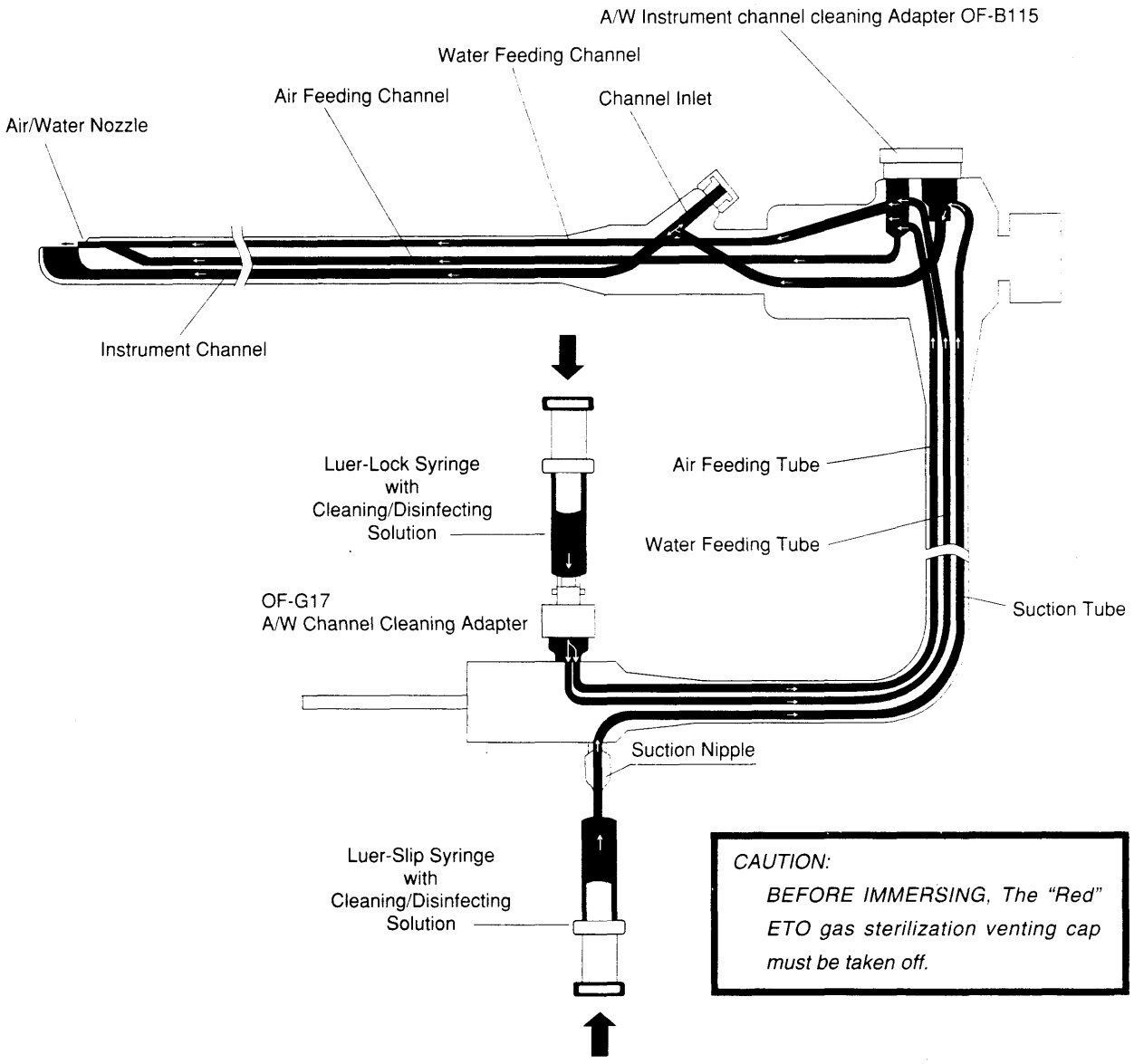
The illustration above shows the actual routes taken by air, water and suction through a Pentax duodenoscope. Please note that all delivery systems have separate independent channels, all of which must first be cleaned with an enzymatic detergent and then exposed to a high-level disinfectant or sterilant.

NOTE:

The new fully enclosed design of the elevator control wire within a PENTAX duodenoseope eliminates the risk of exposure to potentially contaminated patient material.

Therefore, the elevator control wire in PENTAX duodenoscope does not require special reprocessing.

INTERNAL CHANNELS OF A PENTAX DUODENOSCOPE SHOWING COMPLETE PENTAX CLEANING/DISINFECTING SYSTEM



To reprocess a Pentax duodenoscope, first an enzymatic detergent and then a high-level disinfectant or sterilant must be exposed to all internal lumens as well as to all external instrument surfaces and scope components (air/water valve, suction valve, etc.).
Exposure times of detergent and disinfectant/sterilant must be strictly adhered to.

Please note that all solution entrance ports and flow pathways are illustrated above.

NOTE:
Since the elevator control wire is fully enclosed and not exposed to patient material it does not require special reprocessing.

NOTE:
Prior to exposure of all internal channels to an enzymatic detergent and high-level disinfectant (or sterilant), Pentax channels should be manually cleaned with cleaning brushes.

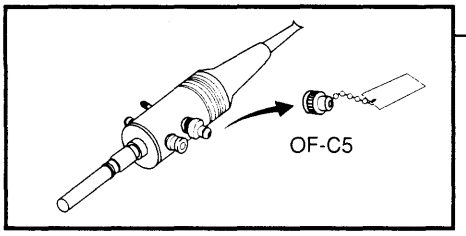
4-1-5 HIGH-LEVEL DISINFECTION

Before any attempt is made to disinfect the endoscope, the complete cleaning procedure described elsewhere in this manual must have been completed.

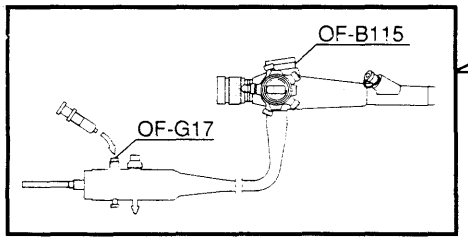
Prior to high-level disinfection, the end user should confirm the minimum effective concentration (MEC) of reused disinfectant, as per the manufacturer's instructions.

Before complete immersion in any disinfecting solution, the endoscope should have been "Leak Tested" as described elsewhere in this manual.

> ⚠ *WARNING:*
>
> *It is imperative that flexible endoscopes and other semi-critical devices be reprocessed using at least high-level disinfection with a legally marketed sterilant/disinfectant. Only legally marketed endoscope automated reprocessing devices/systems whose device specific claims have been validated by the AER manufacturer and/or anti-microbial agents which have been tested and found to be compatible by Pentax should be used with Pentax products.*
>
> *Generally speaking, "2%" and "3.2%" alkaline glutaraldehyde solutions which have been FDA cleared with High-Level Disinfection and/or Sterilization claims are recommended. It should be noted that the actual percentage of active ingredient (glutaraldehyde) in these solutions, as per their product label, may vary from the generic and traditional terms "2% glutaraldehyde" and/or "3.2% glutaraldehyde"*
>
> *For specific brands of compatible disinfectants/sterilants, please contact your local Pentax service facility or sales representative. Please also refer to the inside front cover of this manual regarding infection control.*



> *CAUTION:*
>
> *BEFORE IMMERSING:*
>
> *The 'Red' ETO gas sterilization venting cap must be taken OFF.*



1) The air/water/instrument channel disinfecting adapters consisting of two separate components OF-B115 and OF-G17 should already be installed on the endoscope from the previous cleaning procedure.

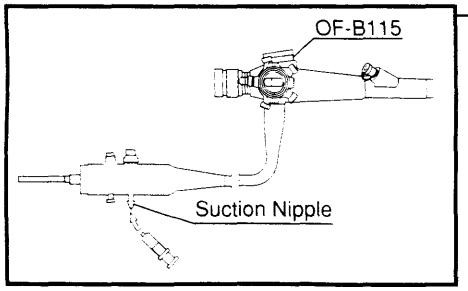
2) a) Model number OF-G17 incorporates a standard ANSI luer lock connector to which a syringe or other device should be attached. Fresh (or reused actively effective) disinfecting solution should be flushed through this connector and will simultaneously flow through both the air and water channels and nozzles of the scope. (Please refer to the internal schematics)

> ⚠ *WARNING:*
>
> *Avoid introduction of air during the flushing process.*
>
> *Confirm that no air bubbles exit from the channel openings at the scope distal tip. The presence of the air bubbles could prevent contact of the disinfectant with channel surfaces.*

b) After the entire scope is completely immersed, and the air and water channels have been filled with disinfecting solution, Model Number OF-G17 should be removed.

c) Adhere to proper exposure times for the disinfectant.

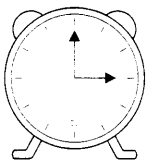
3) Confirm that a rubber inlet seal is attached to the channel inlet during the next step.



4) The suction nipple located on the light guide plug incorporates a standard luer slip fitting to which a syringe (or other device) can be attached. Fresh (or reused actively effective) disinfecting solution should be flushed through or drawn into the entire suction system.

⚠ *WARNING:*

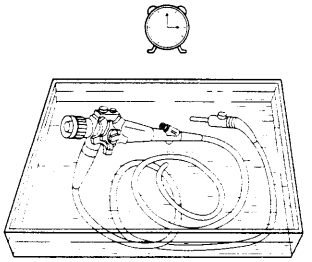
Avoid introduction of air during the flushing process and confirm that no air bubbles exit from the cannel openings at the scope distal tip (or exit from the suction nipple, if aspiration is used.) The presence of air bubbles could prevent contact of the disinfectant with channel surfaces.



Follow exposure times as per product label

⚠ *WARNING:*

It is imperative that ALL internal surfaces of the channels are in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution.



5) As long as the entire instrument is immersed in disinfecting solution, the cleaning adapter, the syringe used in previous steps and the rubber inlet seal should be removed while the instrument remains fully under the disinfecting solution. The removal of component parts and cleaning adapter from the endoscope will eliminate the risk of mated surfaces not being exposed to the liquid chemical germicide.

6) While fully immersed, manipulate valve mechanisms and inject disinfectant via syringe into/through removable scope components. This will remove entrapped air bubbles that could inhibit contact of solution with component surfaces and provide for better exposure of surfaces to germicide. Make sure disinfectant is injected into/through the rubber inlet seal. The endoscope's component parts should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution and accepted by the user as appropriate to accomplish the desired clinical effect.

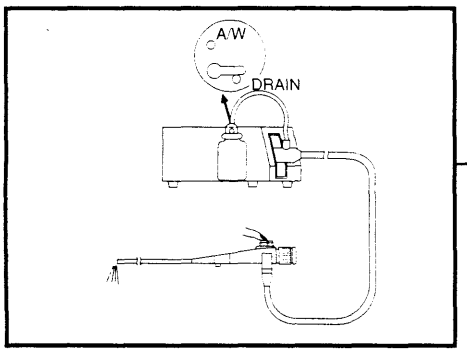
7) After the endoscope and its component parts have been in contact with the disinfecting solution for an appropriate time, flush all channels with air to purge remaining disinfectant, then remove the scope and its components from the solution. Thoroughly rinse the entire endoscope and all its components with sterile water. A syringe filled with sterile water (200mL or more) should be attached to adapter OF-G17 to flush disinfecting solution from the air and water channels of the scope. Fill a syringe with air and flush through the air and water channels several times to force any residual water out of the tubing and nozzles. Dry thoroughly.

8) With the air/water/instrument channel cleaning adapter OF-B115 attached, rinse the entire suction system, including the instrument channel with sterilie water (200mL or more). Flush air through the instrument channel several times to remove residual water. Dry thoroughly.

NOTE:

Ideally, all final rinses should be made with sterile water or bacteria-free water whose microbial quality has been confirmed via monitoring. After water rinsing, 70% alcohol should be flushed through all channels, followed by compressed air, not greater than 165kPa (24 PSI) to facilitate drying. Channel cleaning adapters should be used for alcohol flushing/rinsing and forced air drying. The outer surfaces of the endoscopes can be dried by gently wiping with a sterile gauze or lint-free cloth saturated with alcohol. Regardless of the liquid chemical germicide (sterilant or high-level disinfectant) and/or the quality of the rinse water used, a dry instrument accomplished by a final alcohol rinse followed by forced air is essential to prevent bacteria colonization and/or infections associated with waterborne microorganisms. Such infections are more likely to occur when wet/contaminated instruments are used on patients whose immune systems are compromised or suppressed or when these devices are used in anatomical areas considered sterile and/or susceptible to these organisms.

Following an alcohol rinse, the following steps may be performed to aid in the drying process.

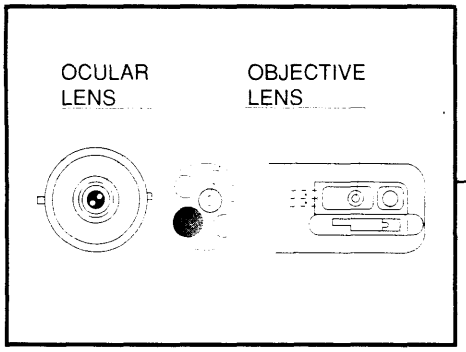


9) Remove the air/water/instrument channel disinfecting adapters, part #OF-B115 and air/water/instrument channel adapter OF-G17, reinstall the previously reprocessed suction control valve, air/water feeding valve, and the rubber inlet seal.

10) Attach the scope to an external suction source, and aspirate air through the channel of the scope to remove any residual alcohol and to air dry channel surfaces.

11) Attach the scope to the light source with the air pump turned ON to its HIGHEST pressure setting and the drain lever of the water bottle set in the DRAIN position, depress the air/water valve of the scope fully until all alcohol has been discharged from the scope. Thoroughly drain all alcohol from the air channel as well by covering the hole in the air/water valve. Repeat until no moisture or alcohol is seen exiting the scope or distal tip.

NOTE:
70% alcohol should be flushed through all channels, followed by compressed air, not greater than 165kPa (1.69kg/cm², 24 PSI), to facilitate drying.



12) Gently dry all external surfaces of the Endoscope with a soft gauze or the like. Do not put tension on the insertion tube while drying since the outer cover of the bending section may be excessively stretched. Dry the objective lens with a cotton-tip applicator.

⚠ *WARNING:*
If the endoscope is to be stored after reprocessing , detach removable valves, components, etc. All channels should be completely dry before storage.

⚠ *WARNING: (in the USA or other countries adhering to FDA regulations)*
It is imperative that semi-critical devices including most flexible endoscopes should be reprocessed using at least high-level disinfection with a legally marketed liquid sterilant cleared as a high-level/disinfectant. Some endoscopes are considered critical devices that should be sterilized with a legally marketed sterilant or sterilization process. Only legally marketed automated endoscope reprocessing devices/systems and cleared anti-microbial agents that have been tested by Pentax and found to be compatible with materials used in Pentax instruments should be used to reprocess Pentax products.
Generally speaking, "2%" and "3.2%" alkaline glutaraldehyde solutions which have been FDA cleared with High-Level Disinfection and/or Sterilization claims are recommended. It should be noted that the actual percentage of active ingredient (glutaraldehyde) in these solutions, as per their product label, may vary from the generic and traditional terms "2% glutaraldehyde" and/or "3.2% glutaraldehyde"
For specific brands of compatible disinfectants/sterilants, please contact your local Pentax service facility or sales representative. Please also refer to the inside front cover of this manual regarding infection control.

4-1-6 DISINFECTION OF ACCESSORIES

⚠ *WARNING:*

Current infection control guidelines require that biopsy forceps and similar endoscopic accessory instruments which enter sterile tissue or the vascular system or break the mucosal barrier must be sterilized before each patient use. It is recommended that any endoscopic accessory instruments intended for use in the biliary tract be subjected to an appropriate sterilization process. For patient contact endoscopic accessories, follow the specific and detailed reprocessing instructions supplied with each product.

CAUTION:

Not all manufacturers of automated endoscope reprocessors (AERs) make specific claims nor provide special instructions for reprocessing all of the removable scope components that are integral to the safe and effective operation of flexible endoscopes. Therefore, should the AER manufacturer's instructions not specifically address reprocessing of any particular scope component (air/water valve, suction valve, irrigation valve, inlet seal, irrigation tube, check-valve, selector mechanism, etc.) in the AER, then those components must be reprocessed manually as described in Pentax instructions/labeling. Prior to use, check with each AER manufacturer as to their specific claims with respect to reprocessing individual endoscope components.

Before any attempt is made to disinfect endoscopic accessory instruments and/or scope components such as bite block, air/water and suction control valve, brushes, etc. the complete cleaning procedure as described elsewhere in this manual, must have been completed. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent high-level disinfection.

1) The entire accessory or component should be immersed in disinfecting solution.
2) Accessory and component surfaces should remain in contact with the disinfecting solution for the time period recommended by the manufacturer of the solution and accepted by the user as appropriate. To ensure better contact, manipulate components such as valves while injecting disinfectant into/onto components surfaces.
3) After the accessories has been in contact with the disinfecting solution for the appropriate amount of time, remove it from the solution.
4) Rinse all residual disinfecting solution from the accessory /component by immersing it under sterile water.
5) After thoroughly rinsing, the accessories should be gently dried using a soft gauze or the like. Compressed air may also be used to facilitate drying.

NOTE:

Ideally, all final rinses should be made with sterile water or bacteria-free water whose microbial quality has been confirmed via monitoring. After water rinsing, 70% alcohol should be flushed through tubing of the endoscopic accessory instruments, followed by compressed air, not greater than 165kPa (24 PSI) to facilitate drying. The outer surfaces can be dried by gently wiping with a sterile gauze or lint-free cloth saturated with alcohol.

Regardless of the quality of the rinse water used, a dry instrument accomplished by a final alcohol rinse followed by forced air is essential to prevent bacteria colonization and/or infections associated with waterborne microorganisms. Such infections are more likely to occur when wet/contaminated instruments are used on patients whose immune systems are compromised or suppressed or when these devices are used in anatomical areas considered sterile and/or susceptible to these organisms.

⚠ *WARNING:*

The addition of defoaming agents to the water supply and/or automated reprocessing system is NOT recommended. Due to their nature, these silicone based agents cling tenaciously to surfaces. Unless they are rinsed very thoroughly, a "barrier" could be created which could reduce the effectiveness of the disinfection/sterilization process. Additionally, repeated use of such defoamers could eventually lead to residual silicone build up resulting in equipment malfunction such as clogged air and water channels.

4-1-7 STERILIZATION AND AERATION

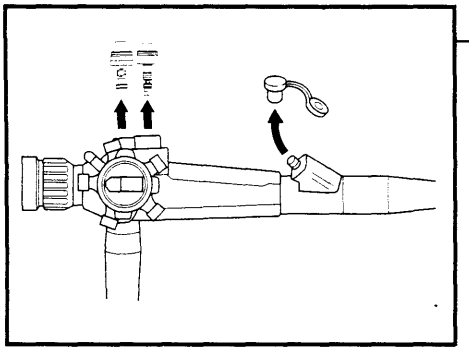
Before any attempt is made to sterilize the fiberscope, the complete cleaning procedure as described elsewhere in this manual must have been completed.

CAUTION:

NEVER place the endoscope in a steam autoclave!! NEVER subject the endoscope to ultrasonic cleaning methods employing high-frequency ultrasound!! Follow provided ETO gas sterilization Parameters.

A) Ethylene Oxide Gas Sterilization

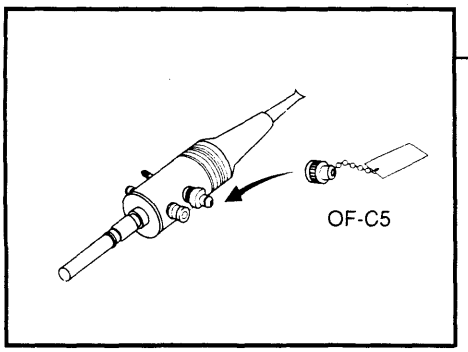
Ethylene Oxide (ETO) Gas Sterilization can be performed on these Endoscopes, provided the following special instructions, which may differ from other endoscopes, are followed to ensure the proper performance of the instrument. Adhere to the sterilization manufacturer's instructions and always use a biological indicator.



1) The endoscope must first have been properly cleaned and thoroughly dried according to the instructions in this manual and each of the component parts such as air/water valve, suction valve, rubber inlet seal, should be removed.

⚠WARNING:

Failure to thoroughly dry all surface areas could result in incomplete or ineffective sterilization. Moisture could prevent contact of the ETO gas with the actual contaminated surfaces.



NOTE:

Prior to placing these Endoscopes in a Gas Sterilizer or Aeration Chamber, the 'Red' ETO gas sterilization venting cap MUST be "ON" securely.

This is opposite of the immersion instructions.

2) The following parameters for Ethylene Oxide Gas Sterilization are proposed.

	20:80 ETO/CO_2	10:90 ETO/HCFC
Temperature:	55°C	55°C
Relative Humidity:	50%	50%
Vacuum:	533mm Hg Actual	533mm Hg Actual
Pressure (Start):	69 kPa (0.70kg/cm², 10PSI)	97 kPa (0.98kg/cm², 14PSI)
EO Concentration :	450mg/L	600mg/L
Pre-Conditioning:	1Hour	1Hour
Gas Exposure Time:	5 Hours	5 Hours
Aeration:	12 Hours at 55°C	12 Hours at 55°C

3) Following ETO Gas Sterilization, aeration time of 72 hours at room temperature is required.

4) Aeration Chamber: To shorten the aeration time to 12 hours, an aeration chamber may be used, provided the temperature does not exceed 55°C (131°F).

CAUTION:

Prior to placing these Endoscopes in an aeration chamber the 'RED' ETO Gas Sterilization Venting Cap MUST be "ON" securely.

9) Other Methods of Sterilization

Other types of cleaning and/or sterilization systems/processes are available for the reprocessing of medical devices. However, due to the heat sensitive nature and/or the specific biocompatible materials used in the construction of flexible endoscopes, some of these marketed systems/processes/solutions could have detrimental effects on flexible endoscopes.

To avoid the potential for instrument damage, confirm the compatibility of such reprocessing systems/solutions with your local Pentax dealer prior to use with any Pentax products.

Prior to using other methods, confirm specific claims of any sterilization methods/processes and ensure manufacturer of such processes has performed microbiological studies that support its claims of achieving sterilization of those specific flexible endoscopes.

4-1-8 STERILIZATION OF ACCESSORIES

⚠ *WARNING:*

Current infection control guidelines require that biopsy forceps and similar accessories which enter sterile tissue or vascular system or break the mucosal barrier must be sterilized before each patient use.

It is recommended that any accessory intended for use in the biliary tract be subjected to an appropriate sterilization process.

For patient contact endoscopic accessories, follow the specific and detailed reprocessing instructions supplied with each product.

CAUTION:

Not all manufacturers of automated endoscope reprocessors (AERs) make specific claims nor provide special instructions for reprocessing all of the removable scope components that are integral to the safe and effective operation of flexible endoscopes. Therefore, should the AER manufacturer's instructions not specifically address reprocessing of any particular scope component (air/water valve, suction valve, irrigation valve, inlet seal, irrigation tube, check-valve, selector mechanism, etc.) in the AER, then those components must be reprocessed manually as described in Pentax instructions/labeling. Prior to use, check with each AER manufacturer as to their specific claims with respect to reprocessing individual endoscope components.

CAUTION:

Use only the type of packaging material and package configuration as recommended by the manufacturer of the sterilizer. Use appropriate heat process indicators and/or biological monitors as recommended by the manufacturer of the sterilizer.

NOTE:

The following sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

Before any attempt is made to sterilize the accessories, the complete cleaning procedure as described elsewhere in this manual must have been completed. Heavily soiled components such as valve mechanisms, inlet seals, etc. should be ultrasonically cleaned prior to subsequent sterilization.

- **ETO GAS sterilization**

1) ETO Gas Sterilization can be performed on these accessories and/or components, provided they have first been properly cleaned and thoroughly dried.
2) Following ETO GAS Sterilization, aeration is required.

NOTE:

For ethylene oxide sterilization of PENTAX accessories and endoscope components, follow the same ETO parameters as for PENTAX endoscopes.

- **Steam Sterilization (Autoclaving)**

NOTE:

The following accessories may be subjected to Steam Autoclaving:

- *PENTAX biopsy forceps with pink handle*
- *PENTAX bite block OF-Z5*
- *PENTAX cleaning brushes for instrument channel*
- *PENTAX cleaning brushes for A/W suction valve cylinder*
- *PENTAX cannula TG1918S*
- *PENTAX A/W instrument channel cleaning adapter OF-B115*
- *PENTAX check-valve OF-B117*
- *PENTAX suction valve OF-B120*
- *PENTAX A/W feeding valve OF-B121*

1) Prior to autoclaving, all autoclavable endoscopic accessory instruments and endoscopic couponents identified above should be thoroughly cleaned using manual and ultrasonic cleaning methods as described elsewhere in this manual.
2) Autoclaving can then be performed under the following conditions:

Sterilizer Type	: Prevacuum
Temperature	: 132 ~ 135°C (270 ~ 275°F)
Time	: 5 minutes

CAUTION:

Use only the type of packaging material and package configuration as recommended by the manufacturer of the sterilizer.

Use appropriate heat process indicators and/or biological monitors as recommended by the manufacturer of the sterilizer.

NOTE:

These sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

CAUTION:

Never place the fiberscope in a steam autoclave nor subject it to ultrasonic cleaning methods!

4-2. POST REPROCESSING

1) Following reprocessing, the endoscope may either be reused or placed in storage.

NOTE:

When utilizing chemo-thermal processes for reprocessing Pentax endoscopes, the instruments should be allowed to return to room temperature prior to use and/or further handling.

2) Prior to reuse, ensure that instrument has been properly inspected and fully prepared for the next clinical procedure.
3) Prior to storage, ensure that all internal channels, scope components, instrument surfaces and accessories are thoroughly dry.
4) A cotton tipped applicator moistened with 70% alcohol may be used to carefully remove any films or residues left upon the lens surfaces, such as the distal objective lens.
5) The endoscope should be hung in a clean, dry, well-ventilated storage cabinet at room temperature. The insertion tube and light guide cable should be hung and kept as straight as possible during storage.

CAUTION:

- *Make sure that all removable components such as the air/water valve, suction valve, forward water jet components, rubber inlet seal(s), and rubber distal tip are detached from the scope. This will allow access for air circulation throughout the internal channels to ensure thorough drying.*
- *Never store the endoscope and accessories in the carrying case, as this type of dark, humid and unventilated environment is conducive to bacteria colonization, which increases the risk of cross contamination. These cases are intended for transportation of the instrument, not storage.*
- *Never store the endoscope in areas of high humidity, high temperatures or in direct exposure to sunlight or X-rays.*
- *Avoid storage of the scope in cabinets, which have any sharp edges, exposed nails/screws, etc. Contact with sharp objects can puncture, scratch or otherwise damage the endoscope.*

4-3. SERVICING

Prior to returning any instrument for repair to Pentax, the instrument should first undergo appropriate reprocessing/decontamination procedures for the purpose of infection control.

1) All instruments requiring repair should be shipped in the original carrying case with appropriate packing along with comments describing the instrument damage and complaint.
2) A repair purchase order number, contact name and phone number of the individual responsible for authorizing repairs, as well as shipping address should be included.
3) Any accessories potentially related to the scope damage or complaint should also be returned with the endoscope.
4) Soaking caps (if applicable) should also be returned with the scope to check/confirm the integrity of their watertight seal.
5) After servicing, all endoscopes must be reprocessed prior to patient use.

> ⚠ *WARNING:*
>
> *Instrument repairs should only be performed by an authorized Pentax service facility. Pentax assumes no liability for any patient/user injury, instrument damage or malfunction, or REPROCESSING FAILURE due to repairs made by unauthorized personnel.*

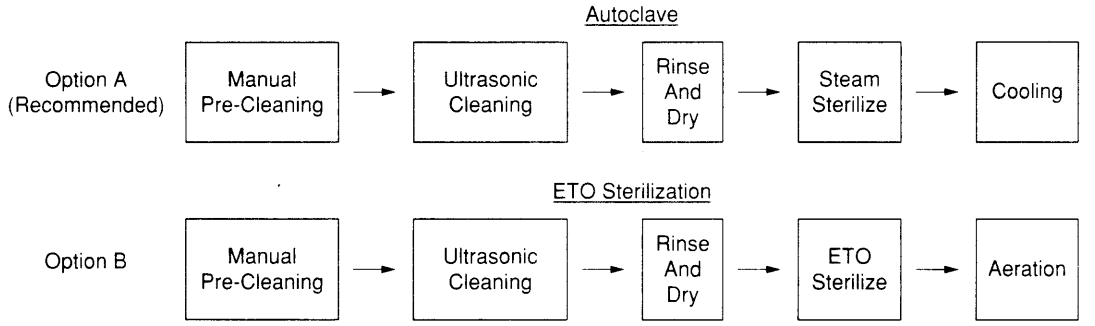
6) For disposal of instruments, follow local or country regulations.

1-4. CARE AND STORAGE OF PENTAX WATER BOTTLE ASSEMBLY Model OS-H4

Each water bottle assembly should be cleaned and sterilized at least on a daily basis or more frequently depending upon the patient and/or type of endoscopic procedure. As with all endoscopic accessories, prior to sterilization, water bottle assemblies must be scrupulously cleaned. Failure to do so could result in incomplete or ineffective sterilization.

I. Cleaning of Water Bottle

Reprocessing At-A-Glance (2 options)



1. After use, the entire bottle assembly (water container, cap and tubing) should be washed with clean running water and a dampened gauze or scrub brush.
2. Ultrasonic cleaning of the entire water bottle assembly is then recommended to access difficult to reach areas, provided the operating frequency is 44kHz ± 6% for a period of 5 minutes.
3. After washing with a cleaning solution, all surfaces of the water bottle assembly should be thoroughly rinsed with clean water and dried. Gauze or cloth can be used to wipe dry most surfaces. Compressed air and 70% alcohol should be used to facilitate drying of hard to reach areas.

Sterilization of Water Bottle

Before any attempt is made to sterilize the water bottle assembly, the complete cleaning procedure described above must have been completed. Failure to scrupulously clean the water bottle prior to the sterilizing process, could result in incomplete or ineffective sterilization.

CAUTION:
Use only the type of packaging material and package configuration as recommended by the manufacturer of the sterilizer.
Use appropriate heat process indicators and/or biological monitors as recommended by the manufacturer of the sterilizer.

NOTE:
The following sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.

Option A: Steam Sterilization (Autoclaving)

Pentax water bottle assembly, Model OS-H4 has been designed to withstand high-pressure steam sterilization procedures providing the following parameters are adhered to:

Sterilizer Type : Prevacuum
Temperature : 132 ~ 135°C (270 ~ 275°F)
Time : 5 minutes

During steam sterilization, ensure that the cap and tubing section have been removed from the water bottle container.
Make sure that the drain lever on the water bottle cap has been set on the A/W position (upright).

NOTE

Do not use the new Pentax OS-H4 water bottle cap with the older OS-H2 water container/bottle. Although the cap may appear to fit onto the bottle, air may escape resulting in insufficient pressure and flow of air and water during the endoscopic procedure. Both the Pentax water bottle cap and bottle (container) are identified by their appropriate model designation. Ensure that an OS-H4 cap is used only with the OS-H4 water container/bottle.

Do not overtighten the bottle cap. Overtighting can cause the bottle cap to break.

Option B: Ethylene-Oxide Gas Sterilization

1. Ethylene Oxide (ETO) gas sterilization can be performed on Pentax water bottles, provided they have first been properly cleaned and thoroughly dried.

⚠ *WARNING:*

Failure to thoroughly dry all surface areas could result in incomplete or ineffective sterilization. Moisture could prevent contact of the ETO gas with the actual contaminated surfaces.

2. The parameters below are proposed for ETO sterilization.

	20:80 ETO/CO_2	10:90 ETO/HCFC
Temperature:	55°C	55°C
Relative Humidity:	50%	50%
Vacuum:	533mm Hg Actual	533mm Hg Actual
Pressure (Start):	69 kPa (0.70kg/cm², 10PSI)	97 kPa (0.98kg/cm², 14PSI)
EO Concentration :	450mg/L	600mg/L
Pre-Conditioning:	1Hour	1Hour
Aeration:	12 Hours at 55°C	12 Hours at 55°C
Gas Exposure Time:	5 Hours	5 Hours

3. Following ETO sterilization, aeration time of 72 hours is required. To shorten the aeration time to 12 hours, an aeration chamber may be used, provided the temperature does not exceed 55°C (131°F).

III. Care During Storage

Prior to storage it is important that no residual water be left within the water bottle assembly. Thoroughly dry all water bottle surfaces to reduce the potential for bacteria colonization during storage. Compressed air and 70% alcohol should be used to facilitate drying, if sterile water was not previously used to rinse the entire water bottle assembly.

CAUTION:

To avoid disconnection and/or bursting of the internal tubing, always set the lever to the Air/Water position (upright) and use less than 165 kPa (1.69 kg/cm², 24PSI) air pressure during forced air drying.

4-5. CARE AND MAINTENANCE TIPS

Flexible endoscopes have been an invaluable tool in the medical community's armamentarium to successfully diagnose and treat a wide variety of illnesses in patients for several decades. Perhaps due to their longevity and progressive design changes over the years which have simplified their use, flexible endoscopes have been somewhat taken for granted and have erroneously not been considered highly technological medical devices.

In fact, current generation flexible endoscopes although easier to clinically use, are much more sophisticated than ever. Special reprocessing instructions must be followed to ensure the instruments are patient ready and patient safe. Special care and handling must be exercised and practiced to prevent instrument malfunction and prolong the reliability of the endoscope.

The burden of responsibility to ensure safe and reliably functioning instruments is left in the hands of the healthcare professionals who actually care for and reprocess flexible endoscopes.

Naturally, equipment manufacturers share in this responsibility and tremendous efforts have been spent in designing instruments which could be reprocessed and maintained as easy as possible. However, due to the nature of their use and application, flexible endoscopes must be subjected to special cleaning procedures, followed by a disinfection or sterilization process after each and every patient use.

To highlight and simplify, what may appear to some as being complicated maintenance and reprocessing instructions, Pentax strongly recommends the users review the following suggestions and advice on the care and maintenance of your Pentax flexible endoscopes.

These tips, particularly those involving scope reprocessing should not be construed as "shortcuts" and are not intended as substitute directions for complete instructions found elsewhere in the owner's manual.

** Avoid soaking of the endoscope with accessories (forceps, injection or aspiration needles, etc.) or any sharp edged objects which could inadvertently scratch or cut the distal bending section sheath. (Subsequent flexing back and forth of the rubber sheath could eventually stretch the scratched rubber until a pinhole and leak develops.)

** Exposure to a compatible enzymatic detergent is essential to thorough cleaning of all surfaces of the endoscope. Rinsing and drying after cleaning is imperative to prevent dilution of the disinfectant/sterilant.

** Do not reuse disposable accessories intended for single patient or one time use.

** Do not expose the endoscope or accessories to harsh chemical solutions. Strictly adhere to exposure times recommended by the manufacturers of compatible solutions.

** Avoid contact of any flexible portion of the endoscope with any sharp edge objects (bed frames, table top corners, sink drains, accessories hanging in storage cabinets, etc.) at any time during the handling, reprocessing or storage of the endoscope.

** Avoid stretching of the bending section rubber sheath at the distal portion of the scope. During mechanical cleaning of the scope with a dampened gauze, do not use excessive force. A gentle back and forth wiping motion should be sufficient to remove gross debris. Subsequent soaking in an enzymatic detergent will clean the remainder of debris.

Disinfectants and sterilants are toxic substances by nature. All residual solution must be thoroughly rinsed and dried prior to each patient use.

** The key to preventing clogged air or water channels/nozzles is to immediately flush the channels with either air pressure or fluid/detergent right after removal from the patient. This should be followed by soaking with an enzymatic detergent.

** Avoid attempting to remove or unscrew scope components which should not be removed. Parts such as the distal portion of the light guide plug and any rubber strain reliefs on either the insertion tube or umbilical cable are essential to the watertight integrity of the instrument. Removal or loosening of these components and subsequent immersion could lead to fluid invasion into the endoscope.

** Check for any sharp edges on all surfaces of an automated cleaning/reprocessing unit which may come in contact with an endoscope. Some units may have sharp edged wire mesh filters and baskets or inlet/outlet ports which could damage your scope.

** Do NOT overtighten the cap to the water bottle assembly. The metal pipe at the top of the Pentax water bottle assembly functions as an inlet port for air from the light source. This inlet pipe should not be used as a leverage tool to tighten the cap to the water container. Overtightening could cause the plastic cap to crack.

** Do NOT forget to confirm that a rubber check-valve has been properly attached to the air/water valve prior to use.

** Make sure that rubber air/water/instrument channel cleaning adapter is securely attached to the top of the air/water and suction valve cylinders.

** Do NOT introduce air bubbles into the scope's internal channels during flushing of cleaning and/or disinfecting/sterilizing solutions as these bubbles could interfere in the effectiveness of the disinfection/sterilization process.

** Do not store the endoscope and accessories in the carrying case as this type of dark, humid and unventilated environment is conducive to bacteria colonization which increases the risk of cross-contamination.

** Prior to each use, check the condition of all accessories.
Do NOT use any accessories with kinked or bent flexible shafts.
Do NOT use forceps with misaligned cups and/or bent needles/spikes.
Do NOT use aspiration or injection needles which are not retractable or whose sharp tips can not be protected.
Do NOT use cleaning brushes without smooth or rounded distal tips.
Do NOT use instruments with exceptionally long rigid sections or whose outer diameter restricts pasage through the instrument channel/channel inlet.
Use of any of the above accessories could result in channel damage and costly repairs.

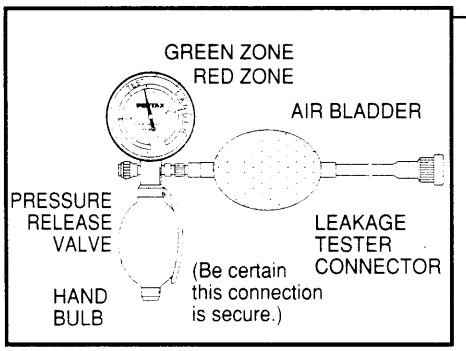
** Verification of the effective level of glutaraldehyde (via test strips or similar methods) is recommended to ensure potency of glutaraldehyde to achieve high-level disinfection.

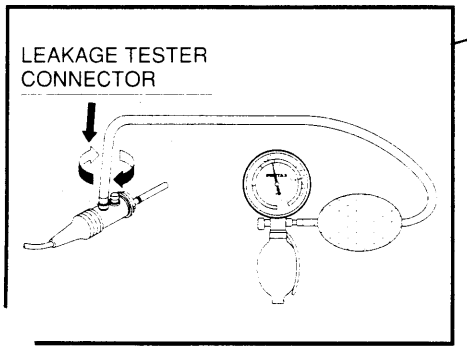
** When utilizing chemo-thermal processes for reprocessing Pentax endoscopes, the instruments should be allowed to return to room temperature prior to use and/or further handling.

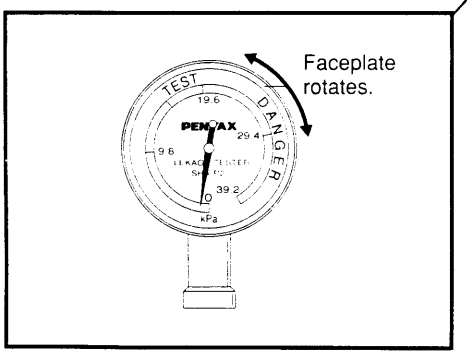
⚠ *WARNING:*
Instrument repairs should only be performed by an authorized Pentax service facility. Pentax assumes no liability for any patient/user injury, instrument damage or malfunction, or ***REPROCESSING FAILURE*** *due to repairs made by unauthorized personnel.*

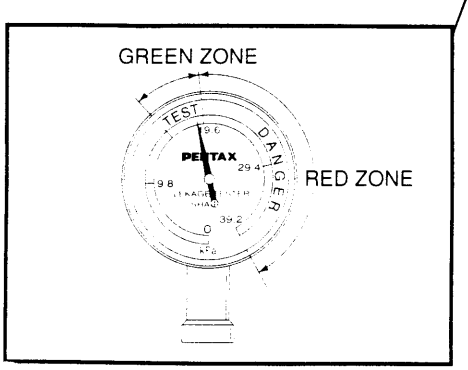
⚠ *WARNING:*
Never drop this equipment or subject it to severe impact as it could compromise the functionality and/or safety of the unit. Should this equipment to be mishandled or dropped, do not use it. Return it to an authorized Pentax service facility for inspection or repair.

LEAKAGE TESTER INSTRUCTIONS









The PENTAX Leakage Tester allows for simple two (2) stage testing of the watertight integrity of the PENTAX Endoscopes. Air pressure is delivered by means of a hand operated bulb, eliminating the need for any electro-mechanical devices.

DRY TEST, STAGE I

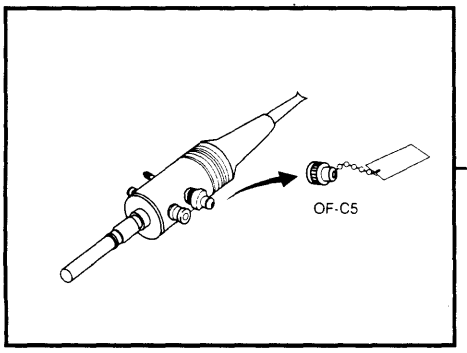
BEFORE IMMERSION, PENTAX Endoscopes should be tested for any major loss of integrity in their watertight construction (example: major tear in the instrument channel). All valves, inlet seals, and other removable components should be detached from the scope prior to leak testing.

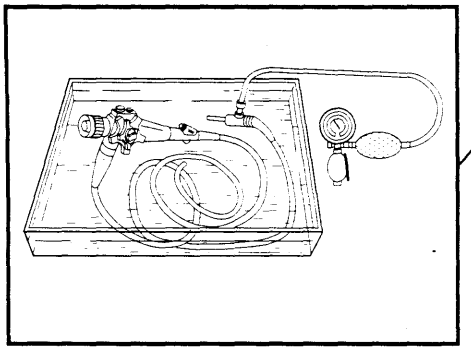
1) Secure the Leakage Tester connector to the air vent on the scope light guide. The Leakage Tester connector and the air vent on the scope light guide MUST be dry before connecting. Proper connection will require alignment of the air vent pin and clockwise rotation of the Leakage Tester connector.
2) Turn the gauge faceplace to 'zero' the pressure indicator.
3) Pressurize the scope by pumping the hand bulb until the indicator on the gauge is in the GREEN zone.
   DO NOT pressurize into the RED zone, as it may cause serious damage to the scope.

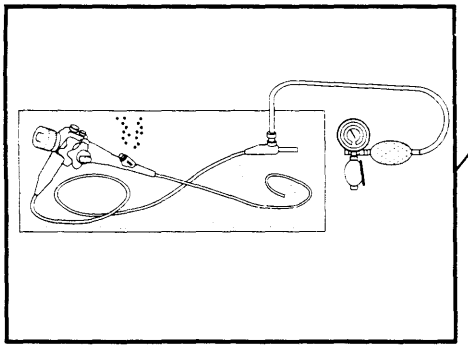
NOTE:
During the leak test procedure, the insertion tube of the scope should be flexed in various positions and the distal bending section should be fully angulated in all directions to confirm the absence of a leak.

4) Observe the gauge pressure to determine if the indicator remains in the GREEN zone. If the indicator drops from the GREEN zone rapidly, a major leak may be indicated.

NOTE:
Be certain that the pressure release valve on the handle of the Leakage Tester has been tightened.
DO NOT IMMERSE the entire instrument, if the gauge indicator does not remain in the GREEN zone. Instead, contact your PENTAX Service Center.







WET TEST, STAGE II

After determining the absence of any major leak in Stage I testing, PENTAX Endoscopes may be immersed to test for loss of integrity in their watertight construction.

CAUTION:

BEFORE IMMERSING:

The 'Red' ETO gas sterilization venting cap must be taken OFF.

1) With the Leakage Tester securely attached to the scope and the scope pressurized with the gauge indicator in the GREEN zone, the entire scope with ALL valves and inlet seals removed may be immersed in clean water.

NOTE:

Only the Leakage Tester connector and a small portion of its tubing should be immersed. NEVER immerse the entire Leakage Tester.

2) Observe the instrument carefully while fully angulating the distal tip of the scope. A few bubbles may occur initially from the recessed areas of the scope. This is normal. If a continuous stream of bubbles is observed from the same spot, a leak is indicated. Immediately remove the scope from the water.
DO NOT use the scope.

3) After removing the scope from water, release the air pressure within the scope by opening the pressure release valve on the handle of the Leakage Tester. After the gauge indicates 'zero', disconnect the Leakage Tester from the scope.

NOTE:

NEVER connect or disconnect the Leakage Tester under water. This will cause leakage of water into the scope and Leakage Tester.

4) If leakage was discovered in step (2), thoroughly dry the instrument and contact your PENTAX Service Center.

5) If no leakage was discovered in step (2), you may proceed with cleaning and disinfection of the scope as described in the Owner's Manual.

SPECIFICATIONS

		FG-16V	FG-24V	FG-29V	FC-38MV FC-38MV2	FC-38FV FC-38FV2	FC-38LV	FS-34V	FD-34V	FD-34V2
Direction of View		Forward-Viewing							Side-Viewing (retro 10°)	Side-Viewing (retro 5°)
Field of View		125°	105°	100°	120°				80°	
Depth of Field		3 ~ 50 mm	3 ~ 100 mm						4 ~ 70 mm	
Diopter		+2 ~ –8 Dptr								
Tip Deflection	Up-Down	180°-180°	210°-120°		180°-180°				120°-90°	
	Right-Left	160°-160°	120°-120°		160°-160°				110°-90°	
Rigid Distal Diameter		5.2 mm	7.8 mm	9.8 mm	13.4 mm			11.5 mm	13 mm	
Insertion Tube Diameter		5.3 mm	7.9 mm	9.8 mm	12.8 mm			11.5 mm	11.3 mm	
Diameter of Instrument Channel		2.0 mm		2.8 mm	3.8 mm			3.5 mm	4.2 mm	
Insertion Tube Working Length		925 mm	1.050 mm		1,300 mm	1,500 mm	1,700 mm	700 mm	1,250 mm	
Total Length		1,270 mm	1,395 mm		1,645 mm	1,845 mm	2,045 mm	1,045 mm	1,595 mm	
Operating environment	Ambient temperature	10 ~ 40°C								
	Relative humidity	30 ~ 85 %								
	Air pressure	700 ~ 1060 hPa								
Storage environment	Ambient temperature	-20 ~ 60°C								
	Relative humidity	0 ~ 85 %								
	Air pressure	700 ~ 1060 hPa								

NOTE: Specifications are subject to change without prior notice and without any obligation on the part of the manufacturer.

CE

0197

このCEマーキングはEC指令への適合宣言マークです。
The CE marking assures that this product complies with the requirements of the EC directive for safety.
Das CE Zeichen garantiert, daß dieses Produkt die in der EU erforderlichen Sicherheitsbestimmungen erfüllt.
Le logo CE certifie que ce produit est conforme aux normes de sécurité prévues par la Communauté Européenne.
Il marchio CE assicura che questo prodotto è conforme alle direttive CE relative alla sicurezza.
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CE 标志意味着保证该类产品遵从欧洲共同体安全法规.

FOR EUROPEAN COUNTRIES

DECLARATION OF CONFORMITY

CE 0197

We, **PENTAX Corporation**
2-36-9, Maeno-cho, Itabashi-ku, 174-8639 Tokyo, Japan
declare under our sole responsibility, that the product:

Product Name : GI FIBERSCOPES
Model Number (S) : FD-34V2, FG-16V, FG-24V, FG-29V, FC-38MV, FC-38MV2
FC-38FV, FC-38FV2, FC-38LV, FS-34V

conforms to the applicable provisions of the Medical Devices Directive 93/42/EEC.

This declaration is made on the basis of: EC quality system approval certificate No. HD961042201 issued by Tüv Rheinland No. 0197 in accordance with Annex II of this Directive.

PENTAX Europe GmbH
Importer into EEA

PENTAX Corporation
Manufacturer

NOTICE

These instruments are used with Class A Medical Equipment (specified EN55011) and are intended for hospital or health care districts.

When used in clinical or residential areas near radio and TV receiver units, these instruments may be subjected to radio interference.

To avoid and resolve adverse electromagnetic effects, do NOT operate these instruments near the RF energy equipment.

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Our representative in your area:

● Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

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